HEARTMATE® SNAP-VE LVAS

Sutures **N**ot **AP**plied **V**ented **E**lectric
Left **V**entricular **A**ssist **S**ystem

INSTRUCTIONS FOR USE

THORATEC®
CORPORATION

6035 Stoneridge Drive
Pleasanton, CA 94588
Tel: 925/847-8600
Fax: 925/847-8574
www.thoratec.com

Emergency HeartLine™ USA: (800) 456-1477
Emergencies outside USA: (925) 847-8600

CAUTION !

Federal (USA) law restricts this device to sale by or on the order of a physician.

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CAUTION !

A thorough understanding of the technical principles, clinical applications, and risks associated with left ventricular support is necessary before using this product. Read this entire *Instructions for Use* and corresponding *Operating Manual* before attempting LVAD implantation. Completion of the HeartMate user-training program, including animal implantation and device operation, also is required prior to using the HeartMate LVAS.

1.0 Device Description

The HeartMate **S**utures **N**ot **AP**plied **V**ented **E**lectric **L**eft **V**entricular **A**ssist **S**ystem (SNAP-VE LVAS) consists of an implanted blood pump, external System Controller, and external power supply components. The blood pump, or Left Ventricular Assist Device (LVAD), is a pusher-plate type device that is capable of producing a stroke volume of 83 ml, generating approximately 10 liters of blood flow per minute, and a beat rate up to 120 beats per minute (bpm).

The **LVAD** consists of a rigid titanium housing, divided in half by a flexible diaphragm. One half of the pump functions as the blood chamber, while the opposite half serves as a chamber for the electric motor. The electric motor is connected to external control and power components via a Percutaneous Tube. Displacement of the diaphragm by rotation of the electric motor results in pumping of the blood.

The **System Controller** is a microprocessor-based unit that initiates motor actuation, monitors and reports on system function, and serves as the primary system interface for users. The System Controller provides two modes of operation:

1) Fixed Rate Mode, and
2) Auto Rate Mode.

LVAD function is adjusted by a switch panel located on the top of the System Controller, or via a separate System Monitor. The System Controller's audio and visual alarms alert users to potentially dangerous conditions, such as low flow or low stroke volume, or depleted Battery power (see *Operating Manual* for full discussion of alarms). The SNAP-VE LVAS is powered (via the System Controller) by either:

1) a pair of wearable, rechargeable Batteries, or by
2) a dedicated power supply device called a Power Base Unit (PBU).

An additional portable, back-up power source - the Emergency Power Pack (EPP) - can be used for periods of extended power outage (e.g., during storms that down power lines). In the event that electric motor actuation is disrupted, the SNAP-VE LVAD may be powered by delivery of a pneumatic pulse (i.e., pulse of air) through the Percutaneous Tube. This pneumatic pulse may be provided by either the HeartMate Hand Pump or an Implantable Pneumatic Drive Console.

2.0 Indications for Use

The HeartMate VE LVAS is indicated for use as a bridge to transplantation in cardiac transplant candidates at risk of imminent death from nonreversible left ventricular failure. The HeartMate VE LVAS is also indicated for use in patients with end-stage left ventricular failure who are ineligible for cardiac transplantation. The HeartMate VE LVAS is intended for use both inside and outside the hospital.

3.0 Contraindication

The HeartMate SNAP-VE LVAS is contraindicated in patients who have a body surface area less than $1.5m^2$.

4.0 Warnings and Precautions

4.1 Warnings

General Warnings

- Do NOT use the Power Base Unit (PBU) in the presence of flammable anesthetic agents, or an explosion could occur.
- Connect the PBU (and any peripheral devices) only to properly tested, grounded, and dedicated alternating current (AC) outlets. Do NOT use an adapter for ungrounded wall outlets, or the risk of electrocution increases.
- Do NOT connect the PBU to an outlet controlled by a wall switch, or the PBU may be left inoperable.
- Do NOT use this device in pregnant women or in any woman likely to become pregnant during her period of LVAS support. A growing fetus will dislodge the pump, which may result in device failure or fatal hemorrhage.
- Do NOT subject patients implanted with the HeartMate SNAP-VE LVAS to Magnetic Resonance Imaging (MRI), as the LVAD contains ferro-magnetic components, and MRI exposure could cause device failure or patient injury.
- Post implant, patients should avoid potential sources of strong static discharges (e.g., television or computer screens), as contact with strong static discharges can damage the electrical parts of the system and cause the LVAD to stop.
- Keep the PBU away from water. If the PBU contacts water or wet surfaces, the SNAP-VE LVAD may stop, or users may receive a serious electric shock.
- Never store the Hand Pump with the bulb in the collapsed position, or the bulb may not work properly when the Hand Pump is needed.

continued

4.1 Warnings continued

Warnings Specific to Implantation

- During the implant process, a complete back-up SNAP-VE LVAS system (SNAP-VE LVAD Implant Kit and external components) must be available on-site and in close proximity to the patient for use in an emergency (e.g., in the event of failure of the primary system or component).
- Prior to advancing the Inflow Valve Conduit into the left ventricle through the Apical Sewing Ring, remove glove tip (previously attached to reduce loss of priming fluid) from the Inflow Valve Conduit and remove Centering Device from the Apical Sewing Ring.
- Prior to advancing the Inflow Valve Conduit into the left ventricle through the Apical Sewing Ring, inspect the ventricle and remove any previously formed clots, or a catastrophic embolism may occur.
- Failure to adequately secure the Inflow Valve Conduit to the Apical Sewing Ring may cause this connection point to loosen, and result in potentially fatal hemorrhage.
- Insure that Thread Protectors have been removed from the Outflow Valve Conduit and Outflow Graft prior to attempting connection, or connection will not be possible.
- All entrapped air must be removed from the LVAD blood-pumping chamber and conduits in order to reduce the risk of air embolus.
- Initial weaning of cardiopulmonary bypass should insure a minimum of two (2) liters per minute (lpm) of blood flow to the SNAP-VE LVAD in order to prevent air embolism.

✎ **Note**: Prolonged deaeration may be due to inadequate blood supply to the SNAP-VE LVAD.

- Failure to adequately tighten the Outflow Valve Conduit and Outflow Graft Screw Rings may allow these connection points to loosen, and result in potentially fatal hemorrhage.
- Do NOT autoclave valve conduits. Doing so will damage the porcine xenograft valves inside.
- A minimum of two (2) fully charged Batteries are required at the time of implantation to power the SNAP-VE LVAS when transporting the patient out of the operating room.
- Never allow fluids to enter the Percutaneous Tube through the Vent Port or Vent Filter, or the pump may stop.

4.1 Warnings continued

Warnings Specific to System Management

- Disconnect Percutaneous Tube and System Controller before using a defibrillator, or the SNAP-VE LVAS could be permanently damaged.

Note: Before connecting or disconnecting the System Controller from the SNAP-VE LVAD, remove all power sources.

- In the event that the SNAP-VE LVAD stops operating, all attempts must be made immediately to restore pump function using electric or pneumatic activation. In the event that the SNAP-VE LVAD stops operating and blood is stagnant in the pump for more than a few minutes (depending on the coagulation status of the patient) there is a risk of stroke or thromboembolism if, or when, the device is restarted.
- Loss of power will cause the SNAP-VE LVAS to stop and blood pumping to cease. Power must be restored immediately. If power cannot be restored, use the HeartMate Hand Pump to perform pneumatic pump activation.
- When the System Controller is disconnected from the Percutaneous Tube, pump function will stop. The System Controller and power must be reconnected as quickly as possible to resume pump function.
- There is a risk of embolism at device explant or reoperation if manipulation of the device or cannulae is performed prior to initiating cardiopulmonary bypass and stopping.
- Do NOT allow the Percutaneous Tube to become contaminated or its inner lumen to become wet, or the pump may stop.

continued

4.2 Precautions

General Precautions

- These *Instructions for Use* address SNAP-VE LVAD handling, preparation, and other perioperative issues. In addition to these *Instructions for Use*, users should read the corresponding *HeartMate SNAP-VE LVAS Operating Manual* for other important guidelines. These manuals are not intended to replace comprehensive laboratory or educational programs, nor appropriate medical judgment.
- Sterile components of the HeartMate SNAP-VE LVAS are intended for single use only. Do NOT reuse sterile LVAS components.
- Patients with mitral or aortic mechanical valves may be at added risk of thrombus accumulation on valves when supported with left ventricular assist devices.
- Use only the HeartMate Power Base Unit (PBU) to charge Batteries. Other battery chargers may damage the Batteries.
- The Power Entry Module on the rear panel of the PBU has been equipped with the proper fuse and set to the appropriate electric mains voltage for your location. Fuse replacement should be performed only by qualified, Thoratec-trained service personnel.
- Connectors should be kept clean and dry. Do NOT expose connectors to water when making or breaking connections.
- Never use tools to tighten connections. Hand-tighten only. Using tools may damage the connectors and cause the pump to stop.

Precautions Specific to Implantation

- Care must be taken to prevent blood from entering and collecting in the inner lumen of valve conduits. Blood on the inner lumen may increase the risk of thromboembolism due to coagulum breaking free in the circulatory system. Thoroughly rinse the inner lumen of valve conduits prior to attaching them to the SNAP-VE LVAD.
- Do NOT over tighten Thread Protectors.
- Do NOT allow the Coring Knife to involve the ventricular septum while performing the core.
- Do NOT remove the Centering Device from Apical Sewing Ring until ready to insert the Inflow Valve Conduit into the left ventricular (LV) apex.

4.2 Precautions continued

Precautions Specific to Implantation

- Do NOT kink the Outflow Graft or position the graft where it could abrade against a pump component or body structure.
- Do NOT clamp the Outflow Graft Bend Relief or a kink may occur. This kink could lead to graft abrasion and blood loss through the graft.
- Do NOT trim or cut the Outflow Graft Bend Relief or a sharp edge may result. This sharp edge could damage the underlying graft material and cause blood loss through the graft.
- Once the SNAP-VE LVAD is activated, rapidly reduce cardiopulmonary bypass flow to provide ample blood flow to the SNAP-VE LVAD. A stroke volume of 70 to 80ml should be achieved and maintained.

Precautions Specific to Patient or System Management

- Diligent care throughout the course of SNAP-VE LVAS support must be exercised to prevent infection and sepsis. Systemic infections and localized infection of the Percutaneous Tube exit site may occur with use of this device. Infection may contribute to patient morbidity and death.
- Right heart failure can occur following implantation of the device. Right ventricular dysfunction, especially when combined with elevated pulmonary vascular resistance, may limit SNAP-VE LVAS effectiveness due to reduced filling of the LVAD.
- A persistent stroke volume of < 30ml may require anticoagulation to prevent possible thrombus accumulation.
- Persistent hypercalcemia in the presence of fungal infection may increase the risk of granular calcium depositation abrading the diaphragm.
- An electro cardiogram (ECG) may be indicated to rule out fibrillation if a patient complains of feeling “different.”
- A change in the sound or motion of the system should initiate evaluation for cause, including the possibility of device malfunction.
- A gurgling or sloshing sound may indicate fluid in the LVAD’s motor compartment. Fluid in the motor compartment can lead to catastrophic LVAD failure; therefore, any gurgling or sloshing sounds should be investigated immediately.

continued

4.2 Precautions continued

Precautions Specific to Patient or System Management

- Physiological factors that affect filling of the pump, such as hypovolemia or postural hypotension, will result in reduced pump flows. Reduced pump flows will persist until such physiological factors are treated or resolved.
- The Percutaneous Tube at explant is not sterile; thus, care must be taken to avoid contamination by limiting the tube's contact with the sterile field. The cut off fingertips of sterile, non-powdered gloves may be placed on the ends of the tube (once cut) to minimize the risk of the tube contacting and contaminating the sterile field.
- When connecting cables, do NOT force together connectors without proper alignment. Forcing together misaligned connectors may damage connections.
- Before connecting or disconnecting the System Controller from the SNAP-VE LVAD, remove all power sources.
- A back-up System Controller, spare Batteries, and the Hand Pump must be with the patient at all times for use in an emergency.
- Using expired or defective Batteries may result in reduced operating time or in abrupt loss of LVAD function.
- To prevent deterioration or damage to Batteries:
  - Do NOT drop or subject Batteries to strong physical shock. Dropped Batteries should be replaced.
  - Do NOT use Batteries in temperatures that are below 15° F (-10°) or above 105° F (+40° C), or Batteries may suddenly fail.
  - Do NOT leave or store Batteries in extreme temperatures (e.g., in cars or car trunks), or Battery life will be shortened.
  - Do NOT directly connect negative and positive Battery terminals.
  - Recharge used Batteries within 12 hours of depletion, or battery life will be shortened.

5.0 LVAS Components

The following components are supplied with the HeartMate SNAP-VE LVAS.

Component Name/Description	Catalog Number
HeartMate SNAP-VE LVAS Implant Kit	1211
HeartMate SNAP-VE LVAS Operating Manual	2653
Power Base Unit (PBU) with Cable	1240
System Controller	1216
Battery Module for System Controller	1264
Rechargeable Battery Set	2025
Battery Holster	1236
Battery Clip Set	1237
VE Display Module	1280N
VE System Monitor	1286
Stroke Volume Limiter	1295
HeartMate Hand Pump	1290
Vent Filter Set	1255
Y – Connector	1218
VE LVAS Emergency Power Pack (EPP)	2020 VE
Travel Case	1260
Shower Kit	1224
Night Belt	1233
Pocket Pak	1235

Note: All system components must be stored in a cool, dry location.

Refurbishment and reuse of blood-contacting titanium components (up to 5 times) is a standard feature of the SNAP-VE LVAD manufacturing process. Accordingly, all HeartMate LVADs may contain refurbished titanium components.

For additional product information and specifications, consult the *HeartMate SNAP- VE LVAS Operating Manual*, or contact Thoratec Corporation.

Note: Thoratec Corporation reserves the right to change specifications without notice.

CAUTION !

Sterile components of the HeartMate SNAP-VE LVAS are intended for single-use only. Do NOT reuse sterile device components.

continued

5.1 Equipment and Supplies Required for Implant

In the operating room, before initiating the implant procedure, open the SNAP-VE LVAS Implant Kit and ensure that the following components are present:

- SNAP-VE LVAD (blood pump) assembly
- System Controller with integral Battery Module
- Outflow Graft Conduit with Bend Relief
- Apical Sewing Ring
- Inflow Valve Conduit
- Outflow Valve Conduit
- Vent Filter
- Y-Connector
- Thread Protectors (one set)
- Coring Knife

In addition to these *Instructions for Use*, the *HeartMate SNAP-VE LVAS Operating Manual* also must be present during the implant procedure.

The following equipment, also necessary for the implant procedure, is supplied by Thoratec Corporation:

Thoratec-Supplied Equipment

Component Name/Description	Catalog Number
• VE Display Module	1280N
• VE System Monitor	1286
• Power Base Unit (PBU) with Cable	1240
• Rechargeable Batteries (1 set, fully charged)	2025
• HeartMate Hand Pump	1290

5.1 Equipment and Supplies Required for Implant continued

The following equipment must be supplied by the hospital implanting the LVAD:

Hospital-Supplied Equipment

- 20cc syringe (no needle) of non-heparinized autologous whole blood
- 60cc syringe (no needle) with 1cc of Heparin
- 1 Small drip basin
- 4 Small bowls of sterile normal saline
- 1 Large basin
- 4 sterile centrifuge tubes
- 2 Emesis basins
- Vent needles
- Autologous serum / un-anticoagulated whole blood
- CV major surgical set
- Heavy non-absorbable ligature
- Catheter-tipped syringe with sterile normal saline

CAUTION !

As a precaution against system malfunction, which cannot be readily corrected by reference to the *Instructions for Use* or *Operating Manual*, a complete SNAP-VE LVAS back-up system (Left Ventricular Assist Device (LVAD) and external components) must be available on-site and in close proximity to the patient for use in an emergency (e.g., in the event of failure of the primary system or of a major system component).

End of Section 1

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6.0 Clinical Studies

Two clinical studies have been performed with the HeartMate VE LVAS. One study included patients who were transplant candidates; the other included non-transplant candidates. The results of these studies are presented below.

6.1 Bridge to Transplant Study

Study Overview

The clinical study for bridge to transplantation was designed to answer two (2) questions:

1) Is the HeartMate VE LVAS a suitable alternative for the HeartMate Implantable Pneumatic (IP) LVAS as a bridge to cardiac transplantation?

2) Is the HeartMate VE LVAS safe for use outside of the hospital?

The primary study endpoints were device flow (pump index) and adverse events. Survival data also were collected.

Enrollment criteria for cardiac transplant candidates to enter the trial:

- Approved cardiac transplant candidate.
- On inotropes.
- On an intra-aortic balloon pump (if possible).
- With left arterial pressure or pulmonary capillary wedge pressure $\geq$ 20 mmHg with either:
  - Systolic blood pressure $\leq$ 80 mmHg, or
  - Cardiac index of $\leq$ 2.0 l/min/m2.
- With reversible end organ dysfunction.

6.1 Bridge to Transplant Study continued

Study Overview cont.

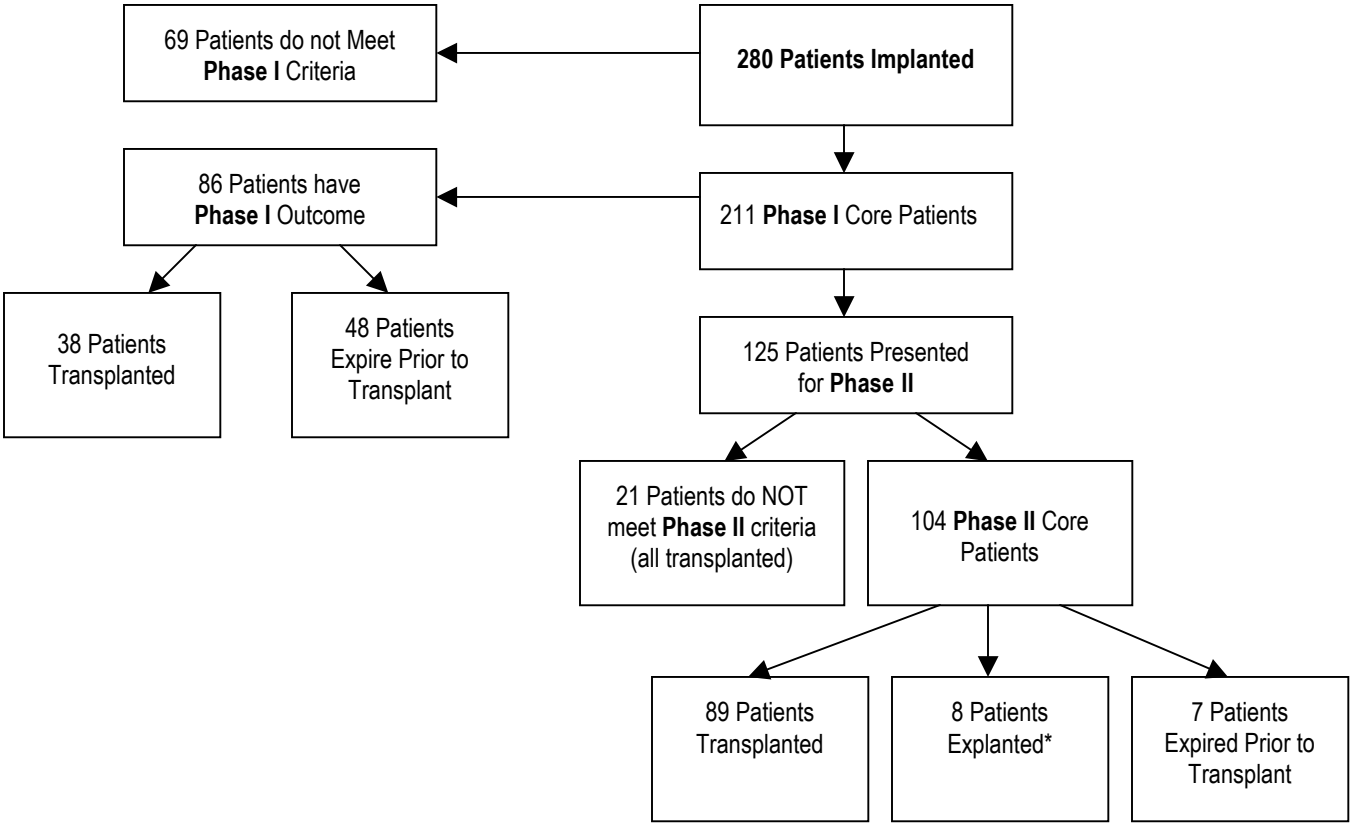
The study group consisted of two (2) phases. **Phase I** included all patients implanted with the device. **Phase II** included those patients eligible to leave the hospital during their wait for a transplant. To enroll into Phase II, patients were at least 14 days post implant and had recovered to New York Heart Association (NYHA) functional class I or II. Patients also were required, upon leaving the hospital, to have a trained companion in the immediate vicinity at all times.

Twenty-four (24) participating US sites contributed 280 patients. Patients (N=69) who were subsequently found to not meet one or more enrollment criteria were included in the analyses of adverse events. The 211 patients who met all criteria (Phase I Core patients) were included in the survival analysis and a subset (N=203) provided the pump flow data. **Figure A** shows the outcomes of all patients entered into the trial. In the 211 Core patients, LVAS support duration ranged from 0 to 685 days, with a mean of 96 days.

Pump flow was measured using the average pump index. The average pump index was $\geq$ 2L/min/m^2 throughout the trial for 198 of 203 (98%) of the Core patients in Phase I and all 125 of the Core patients in Phase II. For Core patients, the average pump index was 2.77 L/min/m^2 in Phase I, and was 3.04 L/min/m2 for core patients in Phase II. The average pump index in the IP study was 2.86 L/min/m^2. Data comparing the IP and VE results are presented graphically in **Figure B**.

6.1 Bridge to Transplant Study continued

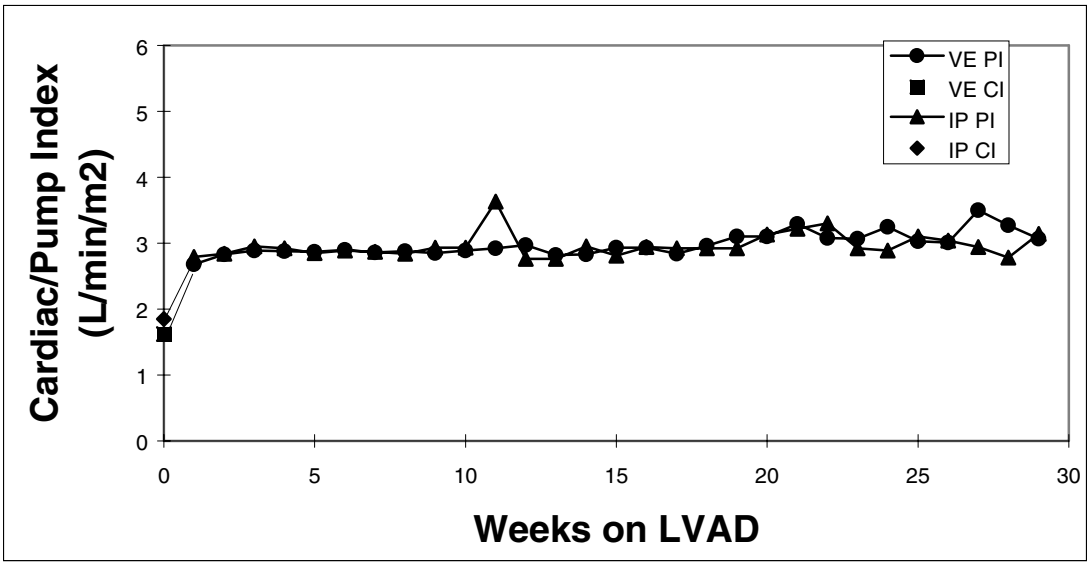
Figure A VE LVAS BRIDGE TO TRANSPLANT CLINICAL TRIAL



*LVAD removed and NOT replaced due to physician's judgment of myocardial recovery.

6.1 Bridge to Transplant Study continued

Figure B Average Pump Index and baseline Cardiac Index values versus time for LVAD patients. Pump index throughout support was significantly greater than Cardiac Index. All values are L/min/m^2.



WEEKS ON IP LVAD											
	Cardiac Index	Pump Index									
	0[1]	1	2	3	4	8	12	16	20	24	28
N	131	110	101	97	91	70	41	24	19	11	6
Median	1.71	2.73	2.77	2.97	2.93	2.79	2.77	2.93	3.09	2.68	2.76
Mean	1.85	2.79	2.84	2.95	2.92	2.84	2.76	2.94	3.13	2.89	2.78
STD	0.56	0.49	0.61	0.59	0.56	0.54	0.58	0.53	0.65	0.89	0.51
SEM	0.05	0.05	0.06	0.06	0.06	0.06	0.09	0.12	0.15	0.27	0.21

WEEKS ON VE LVAD											
	Cardiac Index	Pump Index									
	0[1]	1	2	3	4	8	12	16	20	24	28
N	149	183	174	117	107	55	34	27	18	9	8
Median	1.70	2.60	2.81	2.83	2.87	2.83	3.00	2.78	2.99	3.40	3.31
Mean	1.62	2.68	2.83	2.89	2.88	2.88	2.97	2.93	3.10	3.25	3.27
STD	0.32	0.53	0.51	0.58	0.52	0.58	0.66	0.57	0.68	0.62	0.65
SEM	0.03	0.04	0.04	0.05	0.05	0.08	0.11	0.11	0.16	0.21	0.23

[1] Values measured within 24 hours prior to implantation of LVAD.

6.1 Bridge to Transplant Study continued

Hemodynamic, hematologic, biochemical data, and adverse event data were collected throughout the study. **Table 1** (following page) provides the numbers of adverse events and rates for the VE study and the IP study. **Table 2** provides the adverse event reports for device-related adverse events.

Tables 3 and **4** give similar reports by study phase (i.e., Phase I and II). There were three (3) LVAS failures during the study. The 148 Core patients transplanted included 38 Phase I, 89 Phase II and 21 patients who entered Phase II who did not meet the Phase II criteria. The transplant rate for Core patients is 141/211 (70%). The VE results of survival to transplant are compared to the IP results in **Table 5**. One year post implant, the survival status of VE patients was assessed. **Table 6** compares the one-year post-transplant results for Core IP and Core VE patients who survived to transplant.

6.1 Bridge to Transplant Study continued

Table 1 COMPARISON OF ADVERSE EVENTS IN IP & VE STUDIES
(Adverse Events Independent of Cause)

Adverse Event	IP LVAS N = 223 Pt. Years = 42.4			VE LVAS N = 280 Pt. Years = 86.2		
	Patients	Percent	Events	Patients	Percent	Event
Bleeding	103	46%	145	133	48%	195
Hemolysis	10	4%	10	0	0%	0
Infection Events	105	47%	360	125	45%	290
Thromboembolic Events	8	4%	8	34	12%	44
Right Heart Failure	39	17%	39	31	11%	32
Reoperations	127	57%	285	165	59%	337
Renal Dysfunction*	135	61%	135	158	56%	158
Hepatic Dysfunction*	217	97%	217	263	94%	264
Neural Dysfunction	46	21%	46	75	27%	93
Pulmonary Dysfunction	18	8%	18	5	2%	5
Device Failures	1	<1%	1	3	1%	3
Deaths	75	34%	75	82	29%	82

Table 1 presents the number of patients, percent of patients, and the total number of events for each listed adverse event, comparing the events that occurred in the VE Phase I patients versus events occurring in Phase II patients.

* Includes patients who entered trial with hepatic and renal dysfunction.

Note: The need for reoperation may result from bleeding, infarction, gastrointestinal complications (such as adhesions, perforations, tissue erosion and herniation), or to treat arrhythmias with implantation of a pacemaker.

Neurological dysfunction may result from air emboli, stroke, cerebral vascular accident, temporary ischemic attach, or hypoperfusion. In addition, there is the risk of myocardial or other organ infarction, loss of limb(s), or other vascular obstruction due to embolism. What's more, it is possible that the LVAS will produce *no* significant hemodynamic improvement, and the patient will have been exposed to the risks of cardiothoracic procedure without the benefit of hemodynamic improvement.

6.1 Bridge to Transplant Study continued

Table 2 COMPARISON OF ADVERSE EVENTS IN IP AND VE STUDIES (Device-Related Adverse Events)

Adverse Event	IP LVAS N = 223 Pt. Years = 42.4			VE LVAS N = 280 Pt. Years = 86.2		
	Patients	Percent	Events	Patients	Percent	Event
Bleeding	22	10%	26	31	11%	36
Hemolysis	6	3%	6	0	0%	0
Infection Events	91	41%	286	113	40%	159*
Thromboembolic Events	6	3%	6	17	6%	21
Right Heart Failure	0	0%	0	0	0%	0
Reoperations	28	13%	52	47	17%	71
Renal Dysfunction	0	0%	0	0	0%	0
Hepatic Dysfunction	0	0%	0	0	0%	0
Neural Dysfunction	11	5%	11	14	5%	17
Pulmonary Dysfunction	0	0%	0	0	0%	50
Device Failures	1	<1%	1	3	1%	3
Deaths	1	<1%	1	3	1%	3

Table 2 presents the number of patients, percent of patients, and total number of events for each device-related adverse event, comparing events that occurred in the IP study versus events that occurred in the VE study.

*Number of positive cultures. One infection event may include a number of positive cultures collected to monitor the effectiveness of therapy.

continued

6.1 Bridge to Transplant Study continued

Table 3 COMPARISON OF ADVERSE EVENTS IN PHASE I AND PHASE II
(Adverse Events Independent of Cause)

Adverse Event	VE LVAS PHASE I N = 280; Pt. Years = 33.2			VE LVAS PHASE II N = 160; Pt. Years = 52.9		
	Patients	Percent	Events	Patients	Percent	Event
Bleeding	121	43%	166	20	13%	29
Hemolysis	0	0%	0	0	0%	0
Infection Events	117	42%	230	46	29%	60*
Thromboembolic Events	25	9%	30	11	7%	14
Right Heart Failure	30	11%	31	1	1%	1
Reoperations	146	52%	226	37	23%	71
Renal Dysfunction	149	53%	149	9	6%	9
Hepatic Dysfunction	254	91%	254	10	6%	10
Neural Dysfunction	69	25%	77	12	8%	16
Pulmonary Dysfunction	4	1%	4	1	1%	1
Device Failures	2	1%	2	1	1%	1
Deaths	70	25%	70	12	8%	12

Table 3 presents the number of patients, percent of patients, and total number of events for each listed adverse event, comparing events that occurred exclusively in Phase I versus events occurring exclusively in Phase II.

The substantial difference seen between rates of occurrence of some events in Phase I versus Phase II is due to the increased likelihood of an event occurring in the immediate post-operative period.

6.1 Bridge to Transplant Study continued

Table 4 COMPARISON OF ADVERSE EVENTS IN PHASE I & PHASE II DEVICE-RELATED EVENTS

Adverse Event	VE LVAS PHASE I (N=280; Patient Years = 33.2)			VE LVAS PHASE II (N=160; Patient Years = 52.9)		
	Patients	Percent	Events	Patients	Percent	Events
Bleeding	20	7%	21	12	8%	15
Hemolysis	0	0%	0	0	0%	0
Infection Events	75	27%	105	45	28%	54
Thromboembolic Events	11	4%	11	7	4%	10
Right Heart Failure	0	0%	0	0	0	0
Reoperations	33	12%	43	17	11%	28
Renal Dysfunction	0	0%	0	0	0%	0
Hepatic Dysfunction	0	0%	0	0	0%	0
Neural Dysfunction	11	4%	13	4	3%	4
Pulmonary Dysfunction	0	0%	0	0	0%	0
Device Failures	2	1%	2	1	1%	1
Deaths	2	1%	2	1	1%	1

UCL = 95% Confidence Limit
LCL = 95% Confidence Limit

Table 4 presents the number, percent of patients, and total number of events for each listed adverse event, comparing events that occurred exclusively in Phase I versus events occurring exclusively in Phase II.

continued

6.1 Bridge to Transplant Study continued

Table 5 SURVIVAL TO TRANSPLANT COMPARISON IN IP AND VE STUDIES
(Includes Percent Survival Difference At 95% Confidence Intervals)

	VE LVAS Core Patients N = 211	IP LVAS Core Patients N = 134	Difference (95% CI)
Percent Survival to Transplant	70% (148/211)	71% (95/134)	-0.8% (-10.6%, 9.1%)

Table 6 SURVIVAL COMPARISON 1 YEAR POST TRANSPLANT IN IP &VE STUDIES
(Includes Percent Survival Difference At 95% Confidence Intervals)

	VE LVAS Core Patients N = 143	IP LVAS Core Patients N = 95	Difference (95% CI)
Percent Survival to Transplant	80% (115/143)	81% (77/95)	-0.6% (-10.9%, 9.6%)

For VE: the number of patients who met Phase I inclusion/exclusion criteria and were transplanted prior to April 11, 1999.

6.2 Study for Non-Transplant Candidates

Study Overview

The study that was performed in non-transplant candidates was called Randomized Evaluation of Mechanical Assistance in the Treatment of Congestive Heart failure (REMATCH). This study was conducted by a cooperative agreement between Thoratec Corporation, the National Institutes of Health (NIH), and Columbia University.

The primary objective of the study was to determine the effect of the VE LVAD on all-cause mortality in patients with end-stage chronic heart failure who are on Optimal Medical Management (OMM) and are not candidates for cardiac transplantation. The safety of the VE LVAS was documented by the incidence of adverse events and the incidence of device malfunction and failure.

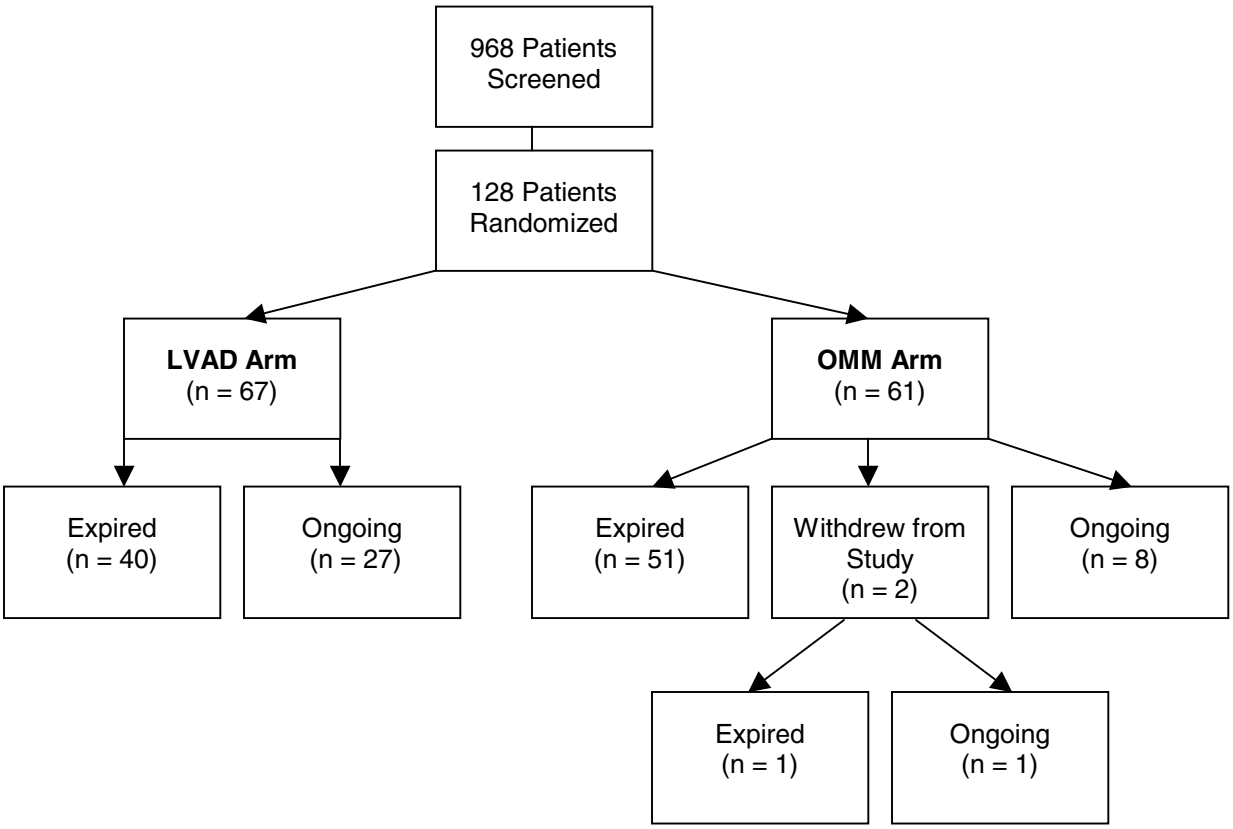
In addition, a number of secondary objectives were evaluated during the REMATCH study, including a comparison of the functional status, quality of life, days alive and out-of hospital, and the incidence of cardiovascular mortality between the two groups.

Patient Population

A total of 128 patients were enrolled into the study at 21 investigational centers in the United States between May 15, 1998 and June 28, 2001. Of the 128 patients enrolled, 67 patients were randomized to the LVAD and 61 patients were randomized to Optimal Medical Management (OMM). See **Figure C** on following page (*Enrollment and Follow Up of 128 Randomized Patients*) for a summary of patient enrollment and outcomes.

6.2 Study for Non-Transplant Candidates

Figure C Enrollment and Follow Up of 128 Randomized Non-Transplant Patients



6.2 Study for Non-Transplant Candidates

Patient Population

The REMATCH patient population included patients who were in end-stage heart failure (NYHA class IV, or class III on IABP or inotropes), who were older than 18 years, and who were not pregnant. The patients were non-transplant candidates due to their age (greater than 65 years), presence of insulin dependent diabetes mellitus with end-organ damage, chronic renal failure, or any major co-morbidity that would make the patient ineligible for cardiac transplantation. The patients were treated with triple drug therapy (digoxin, ACE inhibitor and diuretics) for at least 60 out of the last 90 days.

The patients enrolled into the study were older than patients in previous bridge to transplant studies, with a median age of 69 years (range 34 to 84 years); 80% were male and 20% female; 90% were Caucasian. The majority of patients (74%) had ischemic etiology of heart failure. The majority of patients were in NYHA class IV (98%), and 70% were receiving IV inotropic support at baseline. Other heart failure medications at baseline included: digoxin (86%), ACE Inhibitors (57%) and diuretics (96%). The median baseline LVEF was 18% (range 4 to 25%) and VO2max was 9.5 ml/kg/min (range 3.9 to 13.9). In almost half of the patients the cardiopulmonary exercise test could not be performed due to the patient being dependent on inotropes.

6.2 Study for Non-Transplant Candidates

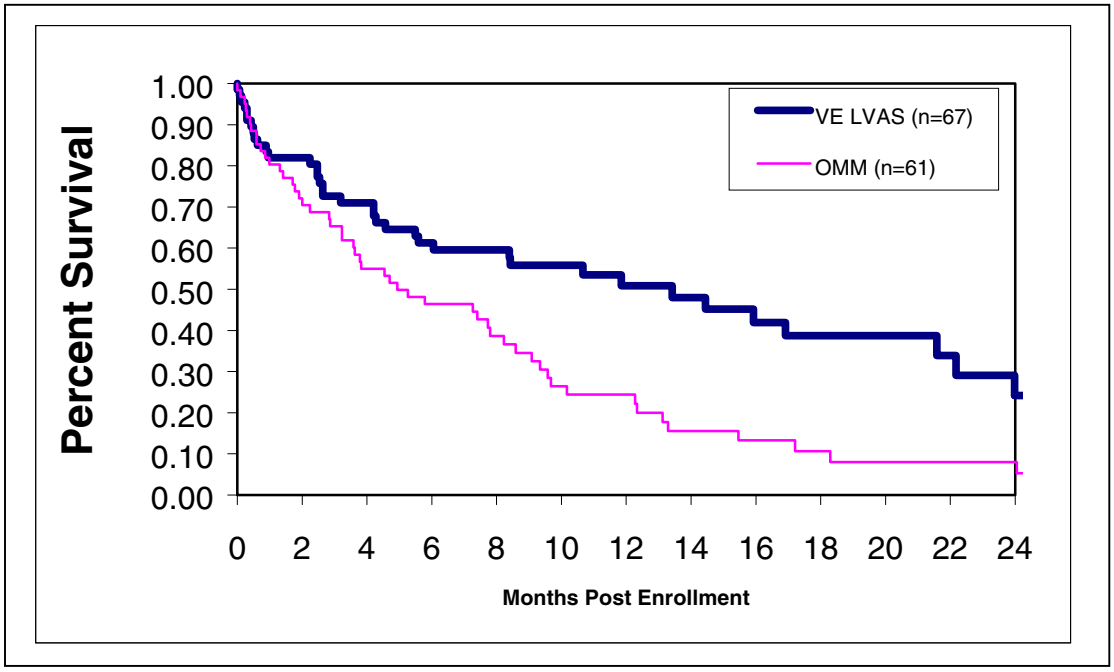
Effectiveness: Survival Advantage of LVADs

Survival data was analyzed using the product – limit method of Kaplan and Meier. Data was analyzed when the predetermined endpoint of 92 overall patient deaths was reached. At the time of the analysis, 27 LVAD and 9 OMM patients remained alive and ongoing in the trial. These patients were censored in the analysis at the study duration they had achieved at the time of the 92 death. Differences in survival distribution between the LVAD and OMM arms were analyzed using a logrank test.

The Kaplan-Meier analysis (see **Figure D** below) showed significantly reduced mortality in the LVAD group (P=0.003). The probability of surviving one year (± standard error) was 50.8 ± 6.7% for the LVAD arm and 24.4 ± 5.9% for OMM patients. Predicted two year survival was 24.2 ± 8.1% for LVAD patients and 8.0 ± 4.1% for OMM patients. Median survival was 408 days for LVAD patients and 150 days for OMM patients.

The Kaplan-Meier analysis conclusively proves the efficacy of the HeartMate VE LVAD in reducing all-cause mortality in patients with end-stage chronic heart failure who are receiving optimal medical management and are not candidates for cardiac transplantation.

Figure D: Kaplan-Meier Plot illustrating the Probability of Survival of LVAD versus OMM Patients After 92 Events. Logrank Analysis: P = 0.003.



See following page for **Table 7**: Kaplan-Meier for ALL Cause Mortality.

6.2 Study for Non-Transplant Candidates continued

Effictiveness: Survival Advantage of LVADs cont.

Table 7 Kaplan-Meier for ALL Cause Mortality.

VE LVAS						
	Time Interval (Months)					
	0 - 1	1 - 3	3 - 6	6 - 12	12 - 18	18 - 24
Number of patients starting interval	67	54	46	36	19	11
Number of patients who died this interval	12	6	7	5	4	3
Number of cumulative patient deaths	12	18	25	30	34	37
Number of patients censored in interval	1	2	3	12	4	3
Number of cumulative censored patients	1	3	6	18	22	25
Probability of surviving interval	0.819	0.726	0.613	0.508	0.387	0.242
+/- 95% Confidence Limit at end of interval	0.09	0.11	0.12	0.16	0.18	0.18
Optimal Medical Management						
	Time Interval (Months)					
	0 - 1	1 - 3	3 -6	6 - 12	12 - 18	18 - 24
Number of patients starting interval	61	49	38	27	11	4
Number of patients who died this interval	12	9	11	11	6	1
Number of cumulative patient deaths	12	21	32	43	49	50
Number of patients censored in interval	0	2	0	5	1	0
Number of cumulative censored patients	0	2	2	7	8	8
Probability of surviving interval	0.803	0.653	0.464	0.244	0.106	0.080
+/- 95% Confidence Limit at end of interval	0.10	0.12	0.13	0.13	0.10	0.09

5 LVAD pts survived beyond 24 months (2 ongoing at 24.5 and 30 months, 3 expired at 24.7 25.7 and 25.9 months) ;
3 OMM pts survived beyond 24 months (1 ongoing at 26.1 months, 2 expired at 24.04 and 24.8 months)

6.2 Study for Non-Transplant Candidates continued

Safety: Adverse Events

The Tables on the following pages (see **Tables 8 – 11**) present the number of patients, percent of patients and the total number of events for each anticipated adverse event in the REMATCH study. There were no unanticipated adverse events. The adverse events are presented as events regardless of severity, and as serious adverse events if they resulted in a fatality, were life threatening, resulted in permanent disability, required hospitalization or prolonged a hospital stay. Due to the differences in survival between the two patient groups, the adverse events are also presented as rates in 100 patient days.

- Overall, the incidence of serious adverse events was 2.74 times as likely to occur to LVAD patients as OMM patients. This, however, did not impact the LVAD patients' survival, functional status or quality of life.
- Confirmed device malfunctions occurred at a rate of 0.10 events / 100 patient days and LVAD failures occurred at a rate of 0.01 events / 100 patient days. There were a total of 2 LVAD failures that occurred in the study.

6.2 Study for Non-Transplant Candidates continued

Safety: Adverse Events cont.

Table 8. Adverse Events Regardless of Severity for Non-Transplant Candidates

	LVAD (n=67)					*OMM (n=61)*				
	# pts	***% pts***	***UCL***	***LCL***	***Events***	***# pts***	***% pts***	***UCL***	***LCL***	***Events***
Neurologic Dysfunction	28	42%	50%	33%	40	4	7%	11%	2%	4
Bleeding	22	33%	41%	25%	43	2	3%	6%	0%	2
Local Infection	44	66%	74%	58%	97	21	34%	43%	26%	32
Sepsis	29	43%	52%	35%	41	9	15%	21%	8%	11
Thromboembolic Event	10	15%	21%	9%	10	2	3%	6%	0%	2
Cardiac Arrest requiring defibrillation	3	4%	8%	1%	6	4	7%	11%	2%	7
Sustained ventricular arrhythmia	18	27%	34%	19%	21	13	21%	29%	14%	21
Supraventricular arrhythmia	17	25%	33%	18%	23	5	8%	13%	3%	6
Syncope	3	4%	8%	1%	3	4	7%	11%	2%	5
Perioperative Myocardial Infarction	0	0%	0%	0%	0	0	0%	0%	0%	0
Non-periop Myocardial Infarction	2	3%	6%	0%	2	1	2%	4%	0%	1
Renal Failure	21	31%	39%	23%	23	6	10%	15%	4%	6
Chronic Renal Dysfunction	0	0%	0%	0%	0	0	0%	0%	0%	0
Hepatic Dysfunction	3	4%	8%	1%	3	0	0%	0%	0%	0
Psychiatric Episode	15	22%	30%	15%	18	3	5%	9%	1%	3
LVAD Related Adverse Events										
LVAD Related Right Heart Failure	10	15%	21%	9%	11					
Perioperative Bleeding	28	42%	50%	33%	32					
Percutaneous or Pocket Infection	29	43%	52%	35%	46					
Pump housing, Inflow , or Outflow Infection	13	19%	26%	13%	16					
Device Thrombosis	7	10%	16%	5%	7					
LVAD Failure	2	3%	6%	0%	2					
Confirmed Device Malfunction	25	37%	46%	29%	70					

Pts = number of patients who experience event

UCL = Upper 95% Confidence Limit

LCL = Lower 95% Confidence Limit

Events = total number of events reported

6.2 Study for Non-Transplant Candidates continued

Serious Adverse Events

Serious adverse events are defined as those that result in a fatality, are life-threatening, result in permanent disability, require hospitalization or that prolong a hospital stay. **Table 9** (following page) summarizes the number and percent of patients who experienced a serious adverse event and the number of events recorded for both the LVAD and OMM groups.

6.2 Study for Non-Transplant Candidates continued

Serious Adverse Events cont.

Table 9 Serious Adverse Events for Non-Transplant Candidates

	LVAD (n=67)					*OMM (n=61)*				
	# pts	***% pts***	***UCL***	***LCL***	***Events***	***# pts***	***% pts***	***UCL***	***LCL***	***Events***
Neurologic Dysfunction	18	27%	34%	19%	22	4	7%	11%	2%	4
Bleeding	17	25%	33%	18%	29	2	3%	6%	0%	2
Local Infection	13	19%	26%	13%	23	5	8%	13%	3%	8
Sepsis	21	31%	39%	23%	25	8	13%	19%	7%	10
Thromboembolic Event	7	10%	16%	5%	7	2	3%	6%	0%	2
Cardiac Arrest requiring defibrillation	3	4%	8%	1%	5	4	7%	11%	2%	6
Sustained ventricular arrhythmia	9	13%	19%	8%	11	8	13%	19%	7%	12
Supraventricular arrhythmia	5	7%	12%	3%	6	2	3%	6%	0%	3
Syncope	2	3%	6%	0%	2	0	0%	0%	0%	0
Perioperative Myocardial Infarction	0	0%	0%	0%	0	0	0%	0%	0%	0
Non-periop Myocardial Infarction	1	1%	4%	0%	1	0	0%	0%	0%	0
Renal Failure	10	15%	21%	9%	10	5	8%	13%	3%	5
Chronic Renal Dysfunction	0	0%	0%	0%	0	0	0%	0%	0%	0
Hepatic Dysfunction	1	1%	4%	0%	1	0	0%	0%	0%	0
Psychiatric Episode	3	4%	8%	1%	3	1	2%	4%	0%	1
LVAD Related Adverse Events										
LVAD Related Right Heart Failure	8	12%	17%	6%	9					
Perioperative Bleeding	23	34%	42%	26%	24					
Percutaneous or Pocket Infection	16	24%	31%	17%	20					
Pump housing, Inflow , or Outflow Infection	9	13%	19%	8%	11					
Device Thrombosis	3	4%	8%	1%	3					
LVAD Failure	2	3%	6%	0%	2					
Confirmed Device Malfunction	11	16%	23%	10%	19					

Pts = number of patients who experience event

UCL = Upper 95% Confidence Limit

LCL = Lower 95% Confidence Limit

Events = total number of events reported

Due to survival differences between the LVAD and OMM groups, adverse events are better compared as event rates. **Table 10** (following page) presents serious adverse events as events per 100 patient days.

6.2 Study for Non-Transplant Candidates continued

Serious Adverse Events cont.

Table 10 Serious Adverse Event Rates per 100 Patient Days for Non-Transplant Candidates

Event	0 - 30 days		31 - 90 days		91 - 180 days		181 - 360 days		> 360 days	
	LVAD	OMM	LVAD	OMM	LVAD	OMM	LVAD	OMM	LVAD	OMM
Neurologic Dysfunction	1.07	0.00	0.19	0.08	0.19	0.04	0.10	0.03	0.07	0.00
Bleeding	0.84	0.00	0.19	0.04	0.21	0.04	0.16	0.00	0.13	0.00
Localized Infection	2.86	0.62	0.55	0.27	0.29	0.25	0.16	0.23	0.22	0.05
Sepsis	0.67	0.19	0.38	0.12	0.16	0.04	0.06	0.13	0.17	0.00
Thromboembolic Event	0.28	0.00	0.03	0.04	0.05	0.00	0.04	0.03	0.00	0.00
Cardiac Arrest requiring Defibrillation	0.11	0.12	0.03	0.16	0.03	0.00	0.04	0.03	0.00	0.00
Sustained ventricular arrhythmia	0.51	0.31	0.13	0.16	0.08	0.11	0.08	0.27	0.02	0.05
Sustained supraventricular arrhythmia	0.73	0.25	0.10	0.08	0.05	0.00	0.04	0.00	0.07	0.00
Syncope	0.00	0.12	0.06	0.04	0.00	0.07	0.00	0.00	0.02	0.00
Perioperative Myocardial Infarction	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Non-perioperative myocardial infarction	0.06	0.06	0.00	0.00	0.00	0.00	0.02	0.00	0.00	0.00
Renal Failure	0.79	0.12	0.03	0.04	0.08	0.04	0.04	0.07	0.07	0.00
Chronic Renal Dysfunction	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Hepatic Dysfunction	0.11	0.00	0.00	0.00	0.00	0.00	0.02	0.00	0.00	0.00
Psychiatric Episode	0.56	0.06	0.13	0.00	0.05	0.04	0.02	0.03	0.02	0.00
LVAD EVENTS										
LVAD Related Right Heart Failure	0.51		0.03		0.03		0.00		0.00	
Perioperative Bleeding	1.40		0.06		0.00		0.04		0.07	
Percutaneous site or pocket infection	0.62		0.48		0.24		0.16		0.07	
Pump housing, inflow or outflow tract infection	0.17		0.16		0.16		0.02		0.02	
Device Thrombosis	0.11		0.03		0.00		0.02		0.07	
Confirmed Device Malfunction	0.22		0.19		0.32		0.54		0.44	
LVAD System Failure	0.00		0.00		0.00		0.00		0.04	

a. Fisher Exact Test (2-tailed)

6.2 Study for Non-Transplant Candidates continued

Quality of Life

The secondary objectives that were studied in both treatment groups included quality of life, functional status, days alive and out-of-hospital, and cardiovascular mortality. These data were compared between the LVAD and OMM groups.

Domain	Visit 1	Visit 3	Visit 6	Visit 12
SF-36				
Physical Functioning	NS	0.0046	0.0197	0.01
Role - Physical	NS	NS	NS	NS
Bodily Pain	OMM	NS	NS	NS
General Health	0.003	<0.0001	0.0007	NS
Vitality	NS	NS	0.0224	NS
Social Functioning	OMM	NS	NS	NS
Role - Emotional	NS	NS	NS	0.0282
Mental Health	NS	NS	NS	NS
Physical Component Summary	OMM	0.0522	NS	NS
Mental Component Summary	NS	NS	NS	NS
Becks Depression Inventory	0.0046	0.0552	0.002	0.0551
Minnesota Living with Heart Failure	NS	NS	0.0177	NS
EuroQOL				
Mobility	NS	NS	0.0068	NS
Self Care	OMM	0.1009	NS	NS
Usual Activity	NS	NS	0.0504	NS
Pain	NS	NS	NS	NS
Anxiety	NS	NS	0.042	NS
General Health	0.004	0.0027	<0.0001	NS
Self Assessment	0.0231	0.0017	<0.0001	NS

NS = Not Statistically Significant

OMM = OMM group significantly better

Although both the LVAD and OMM arms experienced improvements in quality of life when compared to baseline scores, the LVAD group showed significant improvement in physical functioning, perceptions of general health, and depression scores when compared to the OMM group. At **Visit 1**, LVAD patients were recovering from implant surgery. The OMM group showed significantly better quality of life scores that measure body pain and physical functioning during this interval. However, despite this, the LVAD group showed significantly improved perceptions of general health and less depression even in this early interval. From **Visit 3** through **Visit 6**, the LVAD group showed significant improvement over the OMM group in physical function (SF-36, EuroQOl mobility), perception of general

6.2 Study for Non-Transplant Candidates continued

Quality of Life cont.

health (SF-36, EuroQOL), depression (Becks, EuroQOL), and the effect of heart failure on normal activities (Minnesota Living with Heart Failure, SF-36). There were too few OMM patients available to assess to make comparisons valid for **Visit 12**, and on.

In summary, quality of life testing using four validated tests documents that despite major heart surgery and increased adverse event rates, LVAD patients demonstrated improved quality of life when compared to baseline scores and achieved improved quality of life when compared to OMM patients in domains that measure general health, physical functioning and depression.

In summary, the results of the additional secondary objectives are as follows:

- The functional status, as measured by the NYHA class, was significantly improved in the LVAD patients as compared to the OMM patients. Within one month, the LVAD patients had statistically improved functional status, which was maintained through month 12. After month 12 the sample sizes were too small for calculation.
- LVAD patients lived longer and had more days out-of-hospital than the OMM patients.
- Cardiovascular mortality was significantly reduced in the LVAD patients compared to the OMM patients.

6.3 Reliability Evaluation

It is incumbent upon the attending physician to be prepared for eventual device failures, and to anticipate the need for device replacement should patients require treatment for extended periods of time.

The purpose of reliability testing is to obtain a reasonable estimate of how long a given device will perform as intended without failure.

In-vitro reliability testing of 15 VE systems began in July 1997 (range 1 - 4 years). Cumulative test time: 51.4 years. Testing will continue until all systems have failed.

Based on i*n vitro* testing to a confidence interval of 90%, there is 98% chance that this device will be free of critical failures at two (2) months of use; an 88% chance that this device will be free of critical failures at one (1) year of use; and a 76% chance that this device will be free of critical failures at two (2) years of use. The mean-time-to-failure (MTTF) for the device is estimated to be 3.1 years at the 90% confidence interval.

End of Section 2 

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7.0 Implant Procedure

Prior to Implantation

The patient is transported to a cardiovascular operating room, prepped, and anesthetized according to standard procedures. A sternotomy with extended midline abdominal incision is made and cardiopulmonary bypass instituted.

WARNING !

- A minimum of two (2) fully-charged Batteries are required at time of implant to power the LVAS post implant, when transporting the patient out of the operating room.
- Do NOT use the Power Base Unit (PBU) in the presence of flammable anesthetic agents, or an explosion could occur.
- Keep the PBU away from water. If the PBU has contact with water or wet surfaces, the SNAP-VE LVAD may stop or the patient may receive serious electric shock.

7.1 Setting Up and Initializing the System

The HeartMate SNAP-VE LVAS can be configured to operate via the Power Base Unit (**Figure 1**) or Batteries (**Figure 2**).

To set up and initialize the system

1 Plug the Power Base Unit (PBU) into the AC mains (electric outlet), and then turn on the PBU.

2 Connect the System Monitor to the PBU's "Display" socket (back panel), then turn on the System Monitor.

Note: When initialization is complete, "NOT RECEIVING DATA" appears on the System Monitor screen (indicating that the System Monitor is not yet linked to the System Controller).

continued

7.1 Setting Up and Initializing the System continued

3 Insert a minimum of four (4) batteries into the PBU charging slots.

4 Insure that at least two (2) Batteries are fully charged (indicated by green light) so they will be available for patient transport out of the operating room post implant.

CAUTION !

- Only use the HeartMate Power Base Unit (PBU) to charge Batteries. Other chargers may damage Batteries.
- The Power Entry Module on the rear panel of the PBU has been equipped with the proper fuse and set to the appropriate AC mains voltage for your location. Only qualified, Thoratec-trained service personnel should perform fuse replacement.

7.2 Initializing the System Controller

1 Remove System Controller from its sterile package.

Note: A Battery Module (to be installed in the System Controller at a later time) is included in the sterile package.

2 Place System Controller in a safe, sterile location to await later use.

3 Plug the large circular connector-end of the PBU Cable into the rear of the PBU.

4 Pass the ends of the two (2) parallel System Controller Cables out of the sterile field and connect them to the bifurcated ends of the PBU Cable (**Figure 1**).

Note: The PBU and the System Controller will initiate a Hazard Alarm condition (signifying that the System Controller is powered but not connected to the LVAD): The System Controller will display a RED HEART and a YELLOW WRENCH while simultaneously emitting a STEADY audio tone; at the same time, “LOW RATE” (with timer) will appear on the System Monitor screen. These alarms may be silenced and reset by pressing the System Controller’s Alarm Reset Button.

7.2 Initializing the System Controller continued

5 Insure that the system is operating in a Fixed Rate Mode of 50 beats per minute (bpm). If necessary, increase or decrease the rate (i.e., beats per minute) by touching the System Monitor's on-screen arrow keys (↑ or ↓).

6 Disconnect both PBU Cable connectors from the System Controller.

Note: Maintain sterility of System Controller throughout the implant procedure.

CAUTION !

- Once extended outside the sterile field, System Controller connectors should remain outside the sterile field to reduce contamination risk.
- When connecting cables, do NOT force together connectors without proper alignment. Forcing together misaligned connectors may damage connectors.
- Connectors should be kept clean and dry. Do NOT expose connectors to water when making or breaking connections.
- Never use tools to tighten connections. Hand tighten only. Using tools may damage Connectors and cause the pump to stop.

continued

Figure 1 System Controller using the Power Base Unit (PBU). Connections are made in numeric order.

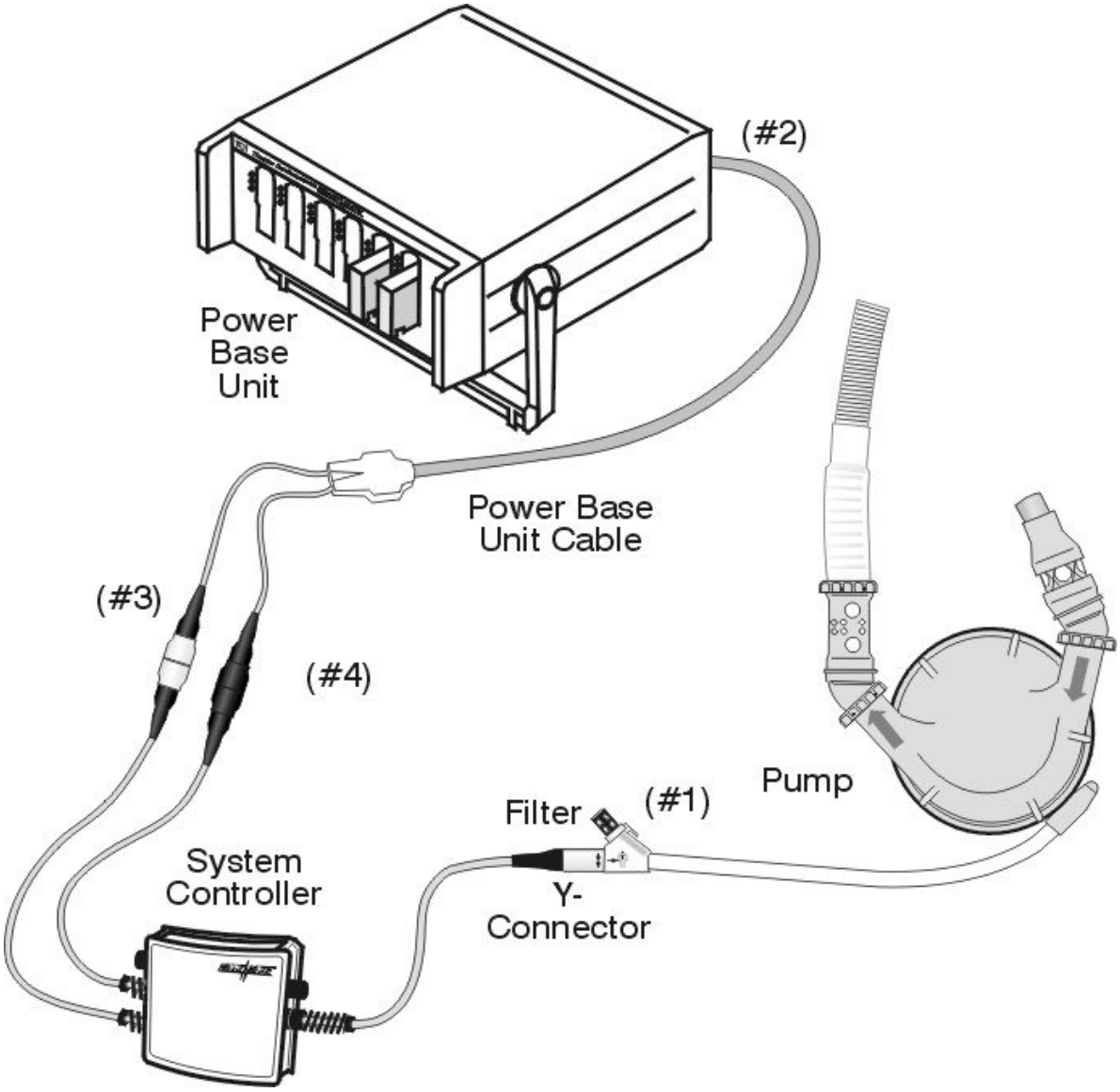
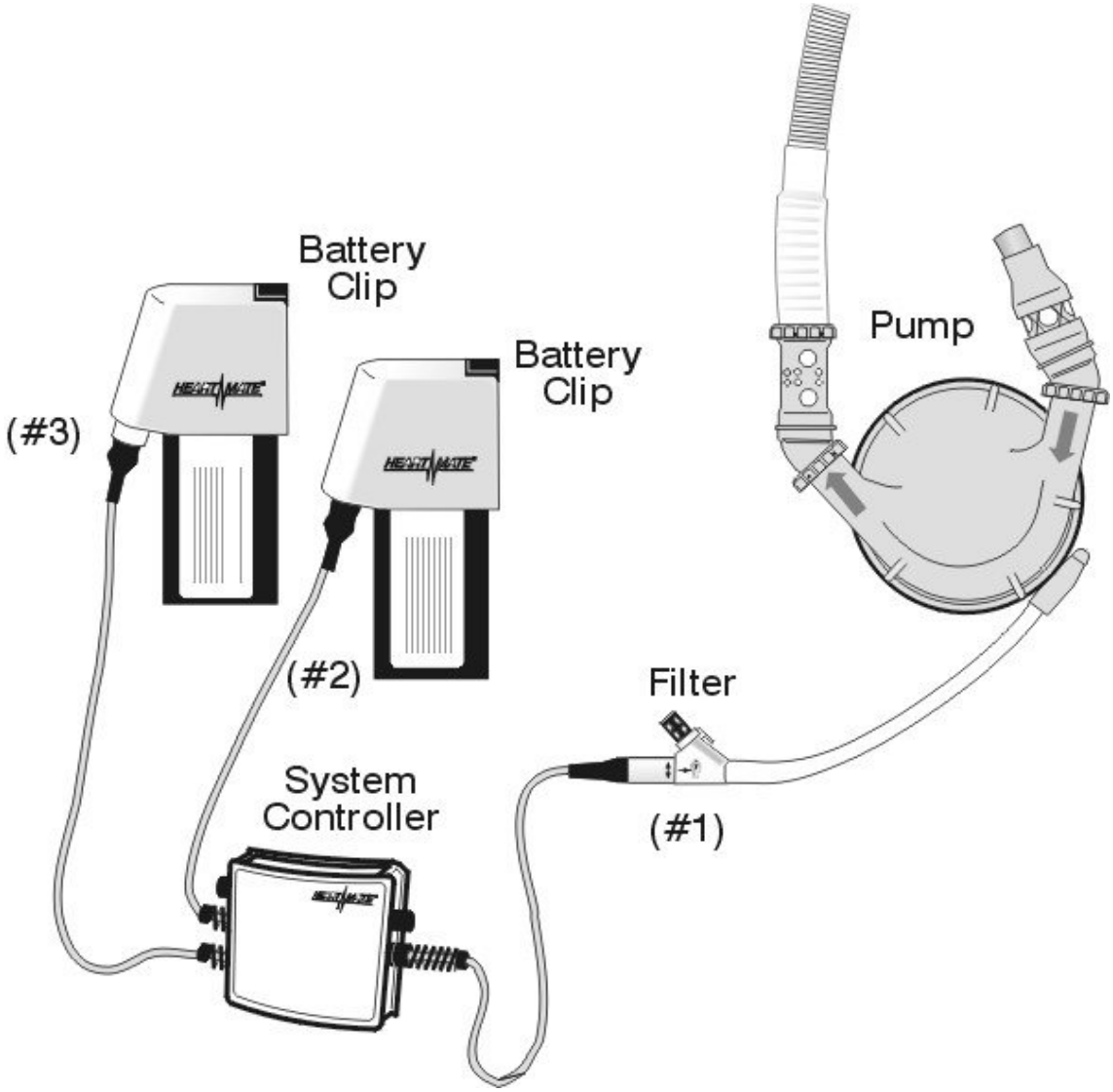


Figure 2 System Connections using Rechargeable Batteries. Connections are made in numeric order.



7.3 Pre-clotting

Prior to use, the external surfaces of the Inflow and Outflow Valve Conduits, as well as the external surface of the Outflow Graft, must be pre-clotted to facilitate hemostasis.

7.3A Pre-Clotting the Outflow Graft Conduit

1 Using strict aseptic technique, remove Screw Ring (with attached Bend Relief) from graft.

2 Set aside Bend Relief (and attached Screw Ring) for later use (i.e., after pre-clotting procedure).

Note: The Screw Ring on the Bend Relief holds a white washer. Ensure the white washer remains inside the Screw Ring.

3 In an emesis basin, evenly coat the *external* surface of graft with serum or other standard pre-clotting agent(s).

4 Drain graft and place it into dry basin.

5 Heat graft in an autoclave to congeal the plasma, if applicable (e.g., if the pre-clotting agent being used requires heat to congeal – not all agents require heat).

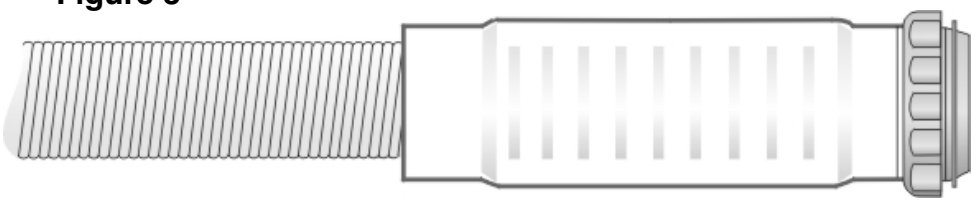
6 Allow heated graft to cool.

7 Once Outflow Graft is pre-clotted, slide Bend Relief and attached Screw Ring (put aside in Step 2) over the Outflow Graft so that the two metal ends overlap (**Figure 3**).

Note: The Screw Ring on the Bend Relief holds a white washer. Insure that washer is inside and correctly positioned before sliding Screw Ring over graft.

7.3A Pre-Clotting the Outflow Graft Conduit continued

Figure 3



8 Place Thread Protector on Screw Ring to prevent contamination of conduit threads.

CAUTION !

Do NOT over tighten Thread Protector.

continued

7.3 Pre-clotting continued

7.3B Pre-clotting the Inflow and Outflow Valve Conduits

The external surfaces of the Inflow and Outflow Valve Conduits must be pre-clotted to reduce the possibility of air entering the patient's circulatory system and of bleeding from the SNAP-VE LVAD during startup.

1 Rinse both Valve Conduits in accordance with standard tissue valve rinse protocol (i.e., rinse 10 minutes in basin one, 3 minutes in basin two, and 3 minutes in basin three).

WARNING !

Do NOT autoclave valve conduits. Doing so will damage the porcine xenograft valves inside.

2 Hold the first valve conduit in a horizontal position over dry basin and slowly expel non-heparinized blood from the syringe onto the *exterior* of the valve conduit graft material. Allow blood to drip into the small basin so that it may be redrawn into the syringe for repeated use.

3 Rotate conduit and continue coating the graft material while allowing blood to clot.

Note: It may take as long as 30 to 40 minutes for an acceptable clot to form in cases of coagulopathy.

4 Repeat Steps 2 - 3 until all visible graft material is covered and coating is complete.

Note: Every 3 to 5 minutes, moisten the porcine xenograft valves by gently dripping (over a separate basin) sterile normal saline into both ends of the valve conduits. This prevents the porcine xenograft valves from drying.

5 Repeat Steps 2 – 4 for second valve conduit.

6 Inspect Inflow and Outflow Valve Conduits for complete coverage. Repeat coating procedure as necessary to ensure complete coverage.

7.3 Pre-clotting continued

CAUTION !

Coat ONLY the EXTERNAL surface of graft material.

7 Immediately after the exterior of each conduit has been completely coated, moisten the porcine xenograft valves with sterile normal saline; then proceed with pump assembly and priming (see 7.4 *Priming the VE LVAD* below).

WARNING !

Care must be taken to prevent blood from entering and collecting in the lumen of the valve conduits. Blood on the inner lumen may increase the risk of thromboembolism due to coagulum breaking free in the circulatory system. Thoroughly rinse the inner lumen of valve conduits before attaching them to the SNAP-VE LVAD.

7.4 Priming the SNAP-VE LVAD

Using strict aseptic technique:

1 Thread the Inflow Valve Conduit into the inflow elbow on the pump body by turning the valve in a clockwise direction.

2 Attach the Outflow Valve Conduit to the outflow side of the pump by turning the Screw Ring on the Outflow Valve Conduit until you hear a clicking sound; and then continue turning until the connection is tight.

Note: Arrows on the SNAP-VE LVAD housing indicate correct orientation of the Inflow versus the Outflow Valve Conduits.

3 Insure that the SNAP-VE LVAD is correctly assembled and that all connections (including Inflow and Outflow Valve Conduit connections) are tight.

4 Insure that the protective “bullet” on the Percutaneous Tube is attached securely to the connector-end of the tube.

5 Place the SNAP-VE LVAD in a large basin to help prevent contamination.

6 Hold the SNAP-VE LVAD in a vertical position.

7 Pour sterile normal saline into the Inflow Valve Conduit until it appears that the SNAP-VE LVAD is full.

WARNING !

Do NOT allow the Percutaneous Tube to become contaminated or its inner lumen to become wet, or the pump may stop.

8 Gently tap the SNAP-VE LVAD to dislodge any air bubbles; rotate the LVAD body to allow all entrapped air to escape through the Outflow Valve Conduit.

9 Hold the SNAP-VE LVAD so the Outflow Valve Conduit is at the highest level, and then continue filling the LVAD through the Inflow Valve Conduit.

7.4 Priming the SNAP-VE LVAD continued

WARNING !

All entrapped air must be removed from the SNAP-VE LVAD blood pumping chamber and conduits in order to minimize the risk of air embolus.

10 Once the SNAP-VE LVAD is completely filled, place the cut-off fingertip of a sterile, non-powered glove over the Inflow Valve Conduit.

11 Place the solid Thread Protector on the Outflow Valve Conduit to prevent gross loss of priming fluid and contamination of conduit threads.

Note: Some fluid leakage will occur through the conduit and connections.

CAUTION !

Do NOT over tighten Thread Protector.

7.5 Implantation

The proper orientation of the implanted components may be seen in **Figure 4**. The Inflow Valve is placed using apical cannulation, and the pump is positioned inferior to the diaphragm.

Preperitoneal Pump Placement *versus* Intra-Abdominal Pump Placement

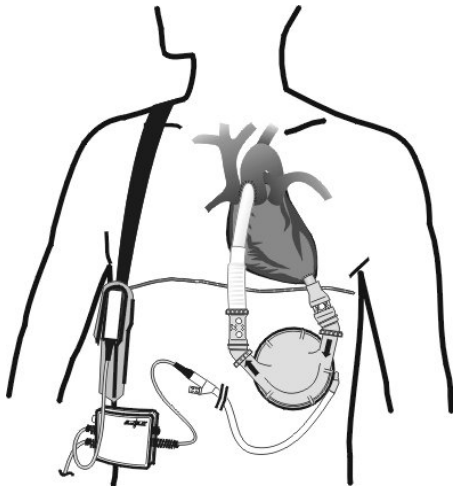
The HeartMate SNAP-VE LVAD may be surgically implanted *either* preperitoneally or intra-abdominally. As described below, the **preperitoneal technique** requires creating a "pocket" for the pump under the posterior rectus sheath and transversalis fascia, and above the rectus abdominis and internal oblique muscles. With the **intra-abdominal technique**, the pump is inserted intra-peritoneally into the left upper abdominal quadrant.

Both techniques have been employed successfully, and either may be used based on the preference of the implanting surgeon. *Potential advantages and disadvantages of each technique are outlined below.*

Preperitoneal Placement

Preperitoneal placement appears preferable for patients who have undergone previous abdominal surgery, or for patients with a short torso. One advantage of the preperitoneal approach is that the device is placed outside the abdominal viscera where bowel adhesions are unlikely. Preperitoneal placement also may lessen the risk of diaphragmatic herniation into the pericardial space and facilitate later explant of the device. Potential disadvantages of the preperitoneal approach include the risk of pocket hematoma, pocket and exit site infection, wound dehiscence, and erosion of the skin overlying the implanted device.

Figure 4 Implanted and worn components of HeartMate SNAP-VE LVAS.



7.5 Implantation continued

Intra-Abdominal Placement
Intra-Abdominal placement may be preferable for thin patients in whom the risk of erosion of the pump through the skin is a concern. Also, thin patients may not accommodate adequate “tunneling” of the Percutaneous Tube (to allow sufficient ingrowth as a barrier to infection). In addition, intra-abdominal placement may be preferable for patients who have been previously treated with an Automatic Implantable Cardioverter Defibrillator (AICD), as the ability to create an intra-abdominal pocket may be hampered by AICD placement. Risks of intra-abdominal placement include diaphragmatic herniation into the pericardial space, wound dehiscence, abdominal (bowel) adhesions, bowel obstruction, bowel perforation, and erosion of the stomach, colon, liver, and abdominal viscera.

7.5A Surgical Technique for PREPERITONEAL Placement

1 Once the sternum is divided, open the left anterior rectus sheath medially and use electrocautery to create a pocket behind the rectus muscle.

2 Extend the dissection laterally.

3 Form a pocket between the posterior rectus sheath and transversalis fascia underneath, and the rectus abdominis and the internal oblique muscles above.

4 Open the pericardium and reflect it laterally to allow exposure of the Left Ventricular (LV) apex.

5 Dissect the peritoneum away from the diaphragm.

6 Perform further dissection as necessary to facilitate insertion of the Inflow Valve Conduit into the LV apex.

7 Once cardiopulmonary bypass is established and the LV apex is prepared for insertion of the Inflow Valve Conduit, pass the Percutaneous Tube from the inferior aspect of the pocket through the subcutaneous tissue to the medial side of the iliac crest. Adjust the pump in pocket as necessary.

continued

7.5 Implantation continued

8 Insert the Inflow Valve Conduit into the LV apex and secure it.

9 Make a small preperitoneal pocket behind the right rectus muscle to accommodate the Outflow Valve Conduit and Outflow Graft.

10 Direct Outflow Graft to ascending aorta.

7.5 Implantation continued

7.5B Surgical Technique for INTRA-ABDOMINAL Placement

1 Make a midline chest incision, extended to the umbilicus.

2 Once cardiopulmonary bypass is instituted and the aorta cross-clamped, prepare left ventricle (LV) apex for insertion of the Inflow Valve Conduit.

3 Place the pump intraperitoneally into the left upper quadrant.

4 Pass the Inflow Valve Conduit through the anterior portion of the diaphragm to allow insertion of the inflow cannula into the LV apex.

5 Place the Outflow Graft Conduit over the diaphragm and Outflow Graft to the ascending aorta in an end-to-side fashion.

6 Externalize the Percutaneous Tube through the left lower quadrant.

7.6 Selecting and Creating a Percutaneous Tube Exit Site

1 Insure that the selected exit site location will not interfere with the clothing (e.g., belts, waistbands).

2 Insure that *at least* 1.0 inch (2.5cm) of the polyester velour covering Percutaneous Tube remains in the subcutaneous tunnel before exiting the skin.

Note: Adherence of the skin to the polyester is essential in minimizing the risk of exit site infection.

3 At the selected exit site, make a circular incision of 0.50 inch (1.3cm) diameter.

4 Form a blunt dissection tunnel from the circular incision site to the pump cavity location.

continued

7.6 Selecting and Creating a Percutaneous Tube Exit Site continued

5 Externalize the Percutaneous Tube through the exit site tunnel.

Note: The “bullet” on the end of the Percutaneous Tube contains a suture tape that can be used to pull the lead through the tunnel. In addition, the bullet tip is threaded and may be attached to tunneling tools of corresponding size.

7.7 Preparing the Ventricular Apex Conduit Site

1 Cut the ligature securing the Coring Knife and remove the plastic plugs from each end.

2 Put the handle through the hole in the Coring Knife cylinder to make a “T” to form a handle.

3 **Chose coring location**: Ideally located slightly anterior to the apex, a few centimeters lateral to the left anterior descending coronary artery.

4 Perform the core with the Coring Knife oriented toward the mitral valve inflow (**Figure 5a**).

CAUTION !

Do NOT allow the Coring Knife to involve the ventricular septum while performing the core.

5 Apply cutting edge of knife to the epicardium and maintain pressure while rotating the Coring Knife back-and-forth, until the ventricular cavity is entered.

6 Remove the core and inspect the ventricle for thrombus.

7 Remove the Apical Sewing Ring from the package and loosen the green ligature.

8 Have an assistant hold the Sewing Ring assembly so that the felt portion is directed toward the heart, and the silicone (tubular) portion is facing outward, away from the heart (**Figure 5b**).

9 Moisten Sewing Ring with sterile normal saline prior to positioning into core for easier removal of the Centering Device.

10 Use at least 12 pledgeted sutures to attach the cuff of the Sewing Ring to the apex (**Figure 5c**).

CAUTION !

Do NOT remove the Centering Device from the Sewing Ring until ready to insert the Inflow Valve Conduit.

7.8 Orientation of the Inflow Valve Conduit

Before implantation, ensure that:

- Outflow Graft is **pre-clotted** on the *external* surface with serum or other standard pre-clotting agent.
- Inflow and Outflow Valve Conduits are **pre-clotted** on their *external* surfaces.
- SNAP-VE LVAD is **correctly assembled** and all joints, including the Inflow and Outflow Valve Conduit connections, are tight.
- SNAP-VE LVAD is completely **primed** with sterile normal saline.
- Outflow Valve Conduit connection is **topped-off** with sterile normal saline.

Orientation of the Inflow Valve Conduit

Selection of the optimal inflow valve orientation at the ventricular apex is important. Care must be taken to avoid excessive angulations of the Inflow Valve Conduit once the SNAP-VE LVAD is *in-situ*. The ideal orientation will allow a straight path from the Inflow Valve Conduit to the SNAP- VE LVAD chamber.

When positioning the inflow cannula, consider the likelihood that the dilated left ventricle may shrink in size as the LVAD assumes its workload.

Once alignment is satisfactory, insert Inflow Valve Conduit into the Apical Sewing Ring and secure with the attached green, non-absorbable suture.

Note: Additional heavy ligatures may be employed to insure that this connection is secure and leak-resistant.

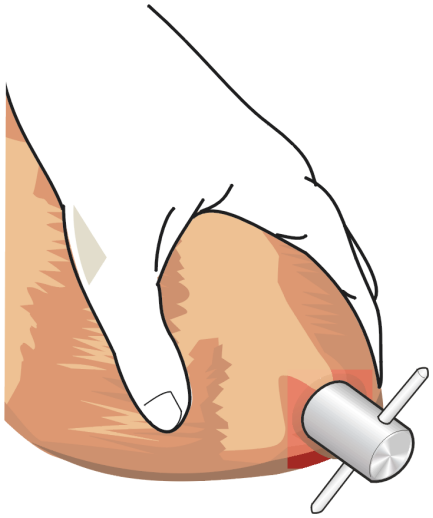
WARNING !

Failure to adequately secure the Inflow Valve Conduit to the Apical Sewing Ring may allow this connection to loosen and lead to potentially fatal hemorrhage.

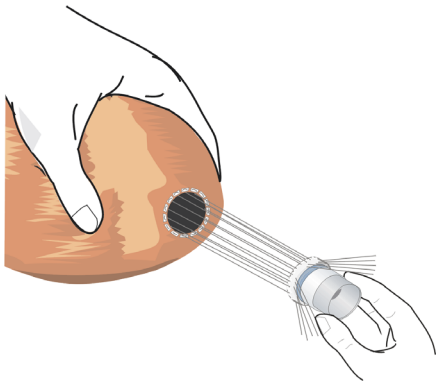
7.8 Orientation of the Inflow Valve Conduit continued

Figures 5a-c Preparing the Ventricular Apex Conduit site.

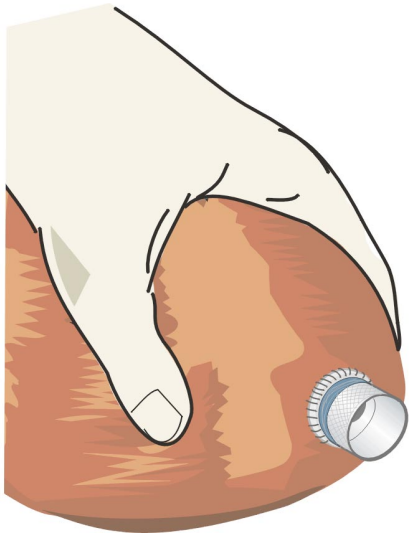
A



B



C



continued

7.8 Orientation of the Inflow Valve Conduit continued

WARNING !

- Prior to advancing the Inflow Valve Conduit into the left ventricle (LV) through the Apical Sewing Ring, remove the glove tip (previously attached to protect sterility and retain priming fluid) from the Inflow Valve Conduit and remove the Centering Device from the Apical Sewing Ring.
- Inspect the ventricle and remove any previously formed clots or a catastrophic embolism may occur.

CAUTION !

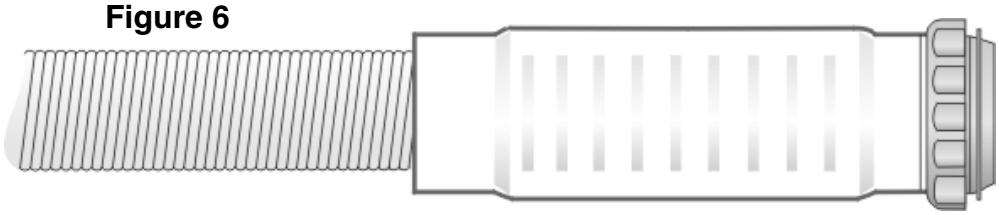
Do NOT twist or pull on the Inflow Valve Conduit assembly; the Valve Conduit and valve leaflets could be distorted and valve function compromised. Hold the conduit by the frame only.

7.9 Attaching the Outflow Graft Conduit

1 Place Outflow Graft Bend Relief into position, over the Outflow Graft, by sliding the Bend Relief over the Outflow Graft, so that the two metal ends overlap (**Figure 6**).

Note: The Screw Ring on the Bend Relief holds a white washer. Insure the washer is inside the Screw Ring and properly positioned prior to attaching the graft to the aorta.

Figure 6



2 Measure and cut the Outflow Graft to the appropriate length.

CAUTION !

Do NOT trim or cut the Outflow Graft Bend Relief or a sharp edge could result. This sharp edge could damage the underlying graft material and cause blood loss through the graft.

3 Anastomose Outflow Graft to the ascending aorta in an end-to-side fashion.

Note: The anastomosis should be non-restrictive. In addition, the suture line should be secure, with no evidence of blood loss.

4 Cross-clamp the graft and, using the Screw Ring, attach the proximal end of the graft to the Outflow Valve Conduit by turning the Screw Ring clockwise.

5 Continue turning the Screw Ring (clockwise) until you hear a clicking sound, and then continue turning until the connection is tight.

Note: Hand-tighten only; do NOT use tools.

CAUTION !

Do NOT clamp Outflow Graft Bend Relief or a kink may occur. This kink could lead to graft abrasion and blood loss through the graft.

continued

7.9 Attaching the Outflow Graft Conduit continued

6 Insure that the connection is tight.

WARNING !

Insure that the Thread Protectors have been removed from the Outflow Valve Conduit and graft before attempting connection, or connection will not be possible.

7 Allow Outflow Graft to back-fill with blood from the aorta before deaereation (see 7.10 *De-Airing the VE LVAD*).

WARNING !

Failure to adequately secure the Outflow Graft Screw Ring may allow this connection point to loosen and result in potentially fatal hemorrhage.

7.10 De-Airing the VE LVAD

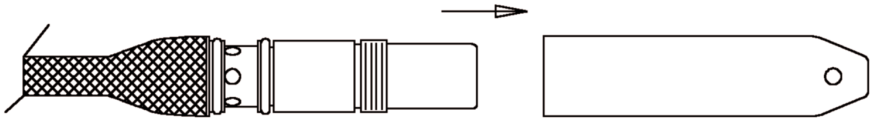
Once the SNAP-VE LVAD is in place and Outflow Graft anastomosis is complete, completely evacuate any residual air from the SNAP-VE LVAD pumping chamber. De-Airing is performed using Hand Pump.

Note: De-airing must be performed prior to electric LVAD activation. Intraoperative transesophageal echocardiography may be used to monitor the presence of air in the aorta. It is advisable to monitor the left atrial pressure, which should be maintained at greater than 10 mmHg.

To connect the Hand Pump*:*

1 After the Percutaneous Tube has been exteriorized, remove the bullet from the tube (**Figure 7**).

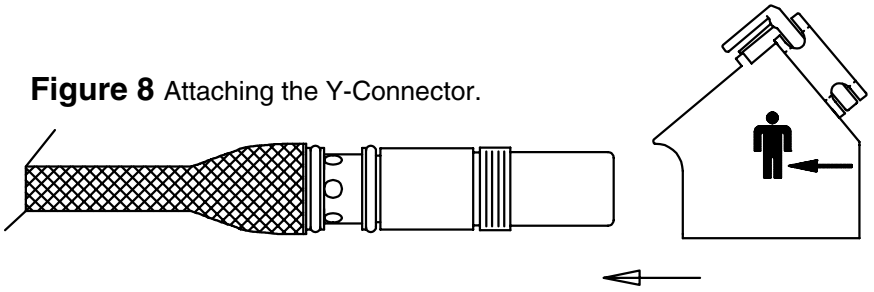
Figure 7 Removing the Bullet.



2 Attach the Y-Connector by sliding the connector fitting completely over the Percutaneous Tube until the connection is snug.

Note: The O-rings on the Percutaneous Tube should be fully engaged into the Y-Connector (**Figure 8**).

Figure 8 Attaching the Y-Connector.



3 Insure proper orientation of the Y-Connector.

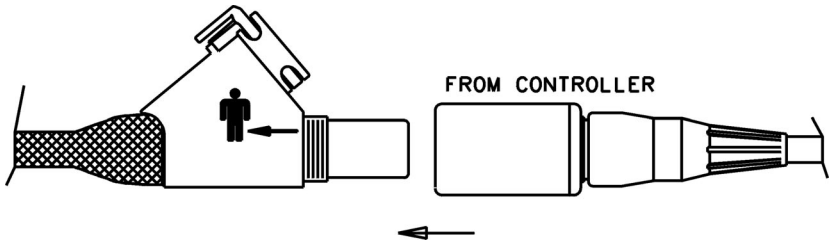
4 Insure that the power leads from the Power Base Unit (PBU) cable to the System Controller are NOT connected.

continued

7.10 De-Airing the VE LVAD continued

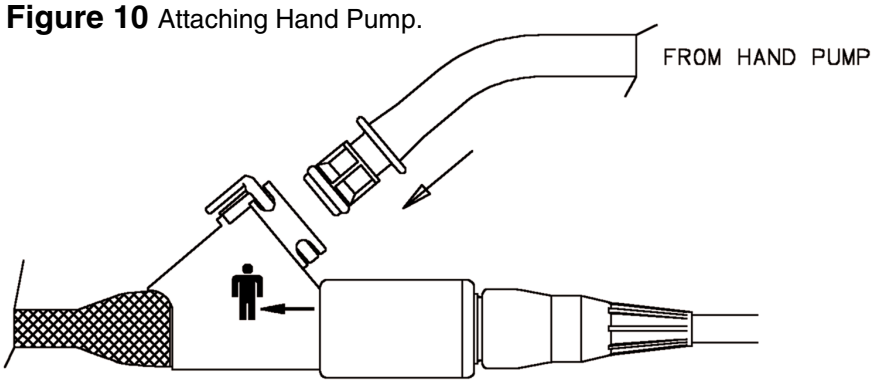
5 Attach the single Percutaneous Tube Connector (from the System Controller) to the pump by aligning the Connectors, pressing them together until *fully engaged*, and then tightening the barrel fitting (**Figure 9**).

Figure 9 Connecting the Percutaneous Tube to System Controller.



6 Attach the HeartMate Hand Pump by inserting the Connector (from the Hand Pump) into the Vent Port on the Y-Connector until you hear a click (**Figure 10**).

Figure 10 Attaching Hand Pump.



7 Cross-clamp the Outflow Graft Conduit at the distal end.

CAUTION !

Do NOT clamp the Outflow Graft Bend Relief or a kink may occur. This kink could lead to graft abrasion and blood loss through the graft.

8 Position the Outflow Graft in a vertical position so an arch forms the highest point.

7.10 De-Airing the VE LVAD continued

9 Insert a vent needle into the Outflow Graft at the highest point in the lumen, between the clamp and the Outflow Graft Conduit connection (anterior side), to optimize air removal.

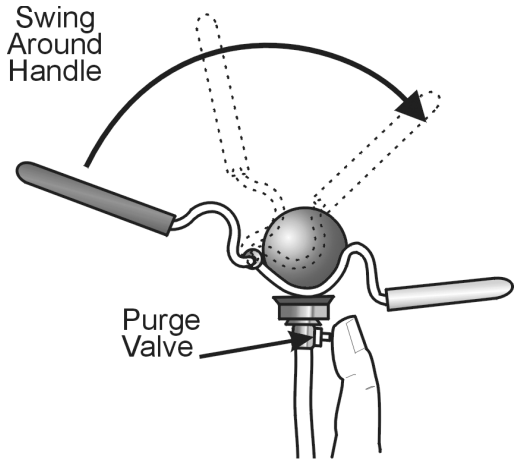
Note: Position vent needle distal to the end of the Bend Relief to allow easy access for later sealing when deaeration is complete. A vent needle also may be place into the ventricular wall to further remove entrapped air. Remove the needle(s) once air is evacuated to eliminate an access point for air re-entry when LVAD operation is initiated. As an additional precaution against air re-entry and possible embolism, the surgical field may be flooded with sterile normal saline.

10 With the cross clamp on the Outflow Graft and graft vent in place, depress the purge valve on the Hand Pump and collapse the bulb (**Figure 11**).

CAUTION !

Do NOT clamp the Outflow Graft Bend Relief or a kink may occur. This kink could lead to abrasion and blood loss through the graft.

Figure 11 Depressing purge valve and collapsing bulb.



11 Release the purge valve and then release the bulb.

Note: The bulb should remain slightly collapsed. The vacuum that the bulb creates causes the diaphragm in the SNAP-VE LVAD to be pulled into its “fill” position.

continued

7.10 De-Airing the VE LVAD continued

12 Wait 10 seconds, then press the purge valve. When the bulb is fully expanded, release the purge valve.

13 Reduce cardiopulmonary bypass flow to allow filling of the left ventricle and SNAP-VE LVAD by diverting at least two (2) liters per minute (lpm) of blood to the ventricle.

Note: A vent needle may be placed into the ventricular wall to further remove entrapped air. Remove the needle once air is evacuated to eliminate an access point for air re-entry once LVAD operation is initiated. As an additional precaution against air re-entry and possible embolism, the surgical field may be flooded with sterile normal saline.

CAUTION !

Before initiation of pumping, remove all vents on the inflow side of the SNAP-VE LVAD, including needles in the pulmonary vein, left atrium, and the left ventricle.

14 Lower patient's head to a Trendelenburg position.

15 Slowly begin actuating SNAP-VE LVAD with the Hand Pump.

Note: If the bulb does not inflate fully between hand pump compression cycles, poor filling of the SNAP-VE LVAD from the ventricle may be the cause. If this occurs, additional bypass flow may be needed to fill the left ventricle; also check the positioning of the Inflow Valve Conduit to ensure that an occlusion is not preventing pump filling.

WARNING !

- All entrapped air must be removed from the SNAP-VE LVAD blood pumping chamber and conduits in order to minimize the risk of an air embolus.
- Disconnect Percutaneous Tube and System Controller prior to using a Defibrillator, or the SNAP-VE system could be permanently damaged.
- Before connecting or disconnecting the System Controller from the SNAP-VE LVAD, remove all power sources.

De-Airing the SNAP-VE LVAD continued

16 When adequate filling of the LVAD is assured, partially remove the Outflow Graft cross-clamp while continuing to manually hand pump the LVAD.

Note: Blood volume should be shifted from cardiopulmonary bypass to the patient to allow for adequate LVAD filling.

17 Continue hand pumping slowly to evacuate all air from the system and to allow the LVAD to fill completely.

WARNING !

Initial weaning of cardiopulmonary bypass should insure a minimum of two (2) liters per minute (lpm) of blood for flow to the SNAP-VE LVAD in order to prevent air embolism. Prolonged deaeration may be due to inadequate blood volume in the pump.

18 Remove the vent needle from the Outflow Graft only when air can no longer be observed exiting through the vent hole.

Note: If air persists for a prolonged period (more than 5 – 10 minutes), rule out leaks at the Inflow Valve Conduit and pump connections. When all air has been removed from the LVAD, initiate electric actuation of the LVAD (see 7.11 *Startup and Weaning from Cardiopulmonary Bypass*).

WARNING !

All entrapped air must be removed from the SNAP-VE LVAD blood pumping chamber and conduits in order to minimize the risk of air embolus.

7.11 Startup and Weaning from Cardiopulmonary Bypass

After slow manual pumping has succeeded in evacuating all air from the system and the SNAP-VE LVAD is filling adequately, fixed rate pumping may begin at 50 beats per minute (bpm).

To begin electric actuation of the LVAD

1 Disconnect the Hand Pump from the vent port by depressing the plastic tab and removing the connector (**Figure 12**).

2 Attach sterile Vent Filter (supplied with pump) to the Y- Connector by inserting it into the Vent Port until fitting snaps into place (**Figure 13**).

WARNING !

Never allow fluids to enter the Percutaneous Tube through the Vent Port or Vent Filter, or the pump may stop.

Figure 12 Disconnecting the Hand Pump.

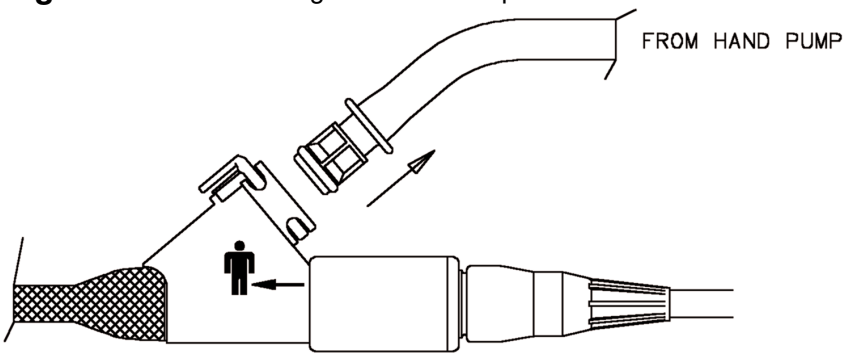
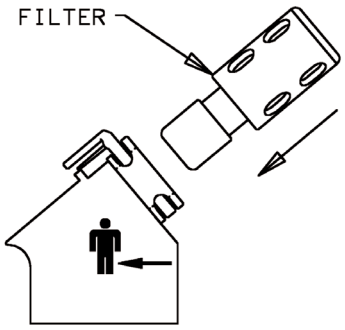


Figure 13 Attaching Vent Filter to the Y-Connector.



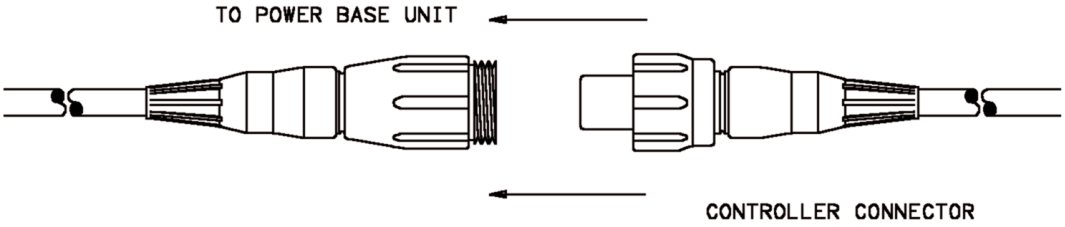
continued

7.11 Startup and Weaning from Cardiopulmonary Bypass continued

3 Connect the **white** connector of the Power Base Unit (PBU) cable to the **white** Connector of the System Controller by aligning the Connectors and tightening the barrel fitting (**Figure 14**).

Note: The SNAP-VE LVAD will immediately begin operation at 50 beats per minute (bpm) and the System Monitor will display LVAD rate, flow and stroke volume while simultaneously indicating the Fixed Rate Mode of 50 bpm.

Figure 14 Connecting System Controller to PBU Cable (white leads first).



To begin electric actuation of the LVAD

4 Connect the **black** connectors in the same fashion as the white connections (Step 3).

Note: The YELLOW WRENCH and once-per-second BEEP will activate (as will the PBU alarm) until the System Controller Battery Module is installed.

5 Reset alarms/advisories by pressing System Controller's Alarm Reset Button.

To begin electric actuation of the LVAD

6 Reduce cardiopulmonary bypass to provide ample blood flow to the SNAP-VE LVAD.

Note: The goal is to achieve and maintain a stroke volume of 70-80 ml.

CAUTION !

Once the SNAP-VE LVAD is activated, rapidly reduce cardiopulmonary bypass flow to provide ample blood flow to the LVAD. A stroke volume of 70-80ml should be achieved and maintained.

continued

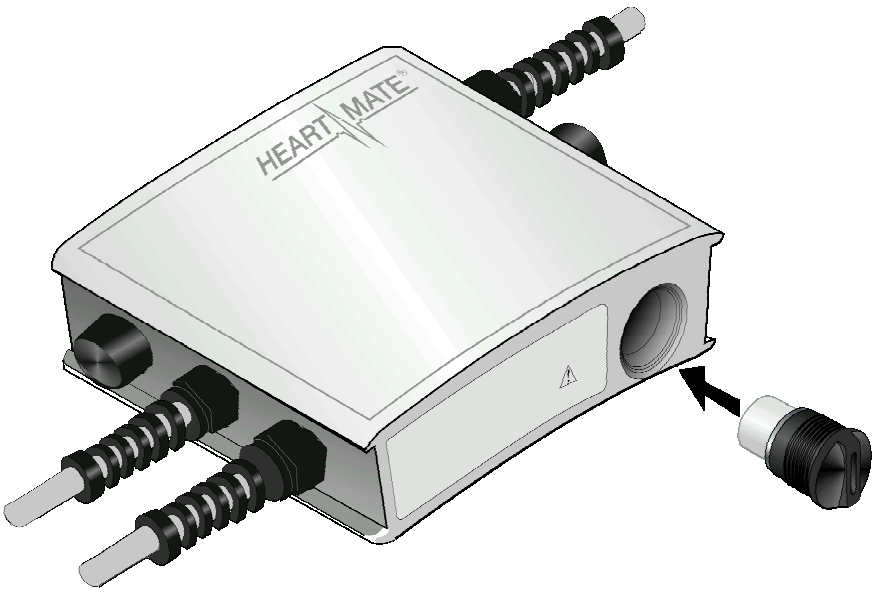
7.11 Startup and Weaning from Cardiopulmonary Bypass continued

7 To eliminate the System Controller Battery Module alarm, insert the Battery Module into the rear of the Controller and screw it in (clockwise) until it is finger-tight (**Figure 15**). Do NOT use tools, a coin, or other similar flat object to insert or tighten the Battery Module. Do NOT over tighten – HAND TIGHTEN ONLY.

Note: The Battery Module enables the System Controller to sound (a steady tone) if the System Controller loses power while connected to the patient. At this point, no further alarms/advisories should occur.

8 Complete weaning from cardiopulmonary bypass and increase LVAD rate and flow.

Figure 15 Inserting Battery Module.



7.12 Anchoring the Pump

Eyelets on the SNAP-VE LVAD housing serve as attachment points for immobilizing the LVAD *in-situ*. Once the LVAD has been inserted and deaerated, it must be sutured to the abdominal wall or surrounding fascia using hospital-supplied non-absorbable sutures.

Failure to suture the SNAP-VE LVAD into place may lead to its movement or migration in the body. This displacement may damage the inflow valve(s), Percutaneous Tube, or Outflow Graft, or traumatize the anastomosis site, resulting in their failure and patient injury or death.

WARNING !

The SNAP-VE LVAD must be sutured securely into position to prevent pump movement or migration and possible patient injury or death.

CAUTION !

The Outflow Graft must NOT be kinked or positioned where it could abrade against a pump component or body structure.

Note: Once pump is immobilized, close incisions in standard fashion.

7.13 Transferring the Patient Out of the Operating Room

When it is time to transfer the patient out of the operating room, the SNAP-VE LVAS should be switched from PBU to Battery power.

To effect the transfer:

1 Insert a Battery into each of the two (2) Battery Clips.

2 Unplug either one of the System Controller connectors from the PBU cable and connect it to one of the Battery Clips.

Note: The alarm indicating PBU disconnection will sound.

3 When the disconnect alarm ceases, unplug the remaining System Controller Connector from the PBU cable and transfer it to the second Battery Clip.

Note: The disconnect alarm should again cease.

4 Tuck Batteries safely beside the patient so that the System Controller leads are not under strain.

CAUTION !

Use of expired or defective Batteries may result in reduced operating time or abrupt loss of SNAP-VE LVAD function. To prevent deterioration or damage to Batteries:

- Do NOT drop or subject Batteries to strong physical shock. Dropped Batteries should be replaced.
- Do NOT use Batteries in temperatures that are below 15° F (-10°) or above 105° F (+40° C), or the Batteries may fail suddenly.
- Do NOT leave or store Batteries in extreme temperatures (e.g., in cars or car trunks), or Battery life will be shortened.
- Do NOT directly connect negative and positive Battery terminals.
- Recharge used Batteries within 12 hours of depletion, or battery life will be shortened.

Note: Because the ability to receive stroke volume and flow data is lost during patient transport (when System Controller is no longer attached to PBU), a portable pressure monitor is usually used when transporting patients out of the operating room to gauge effectiveness of the HeartMate SNAP-VE LVAS immediately post implant. When the patient arrives in the CICU, the LVAS should be re-attached to the PBU and System Monitor (one System Controller lead at a time).

End of Section 3

8.0 Patient Management

In-hospital support of a HeartMate SNAP-VE LVAS patient requires the following equipment:

Equipment	Primary (required)	Back-Up (required)	Optional
Implanted SNAP-VE LVAD	X	--	--
System Controller	X	X	--
Rechargeable Batteries (2 sets)	X (2 sets)	--	X
Battery Clips	X	--	X
HeartWear Accessories*	X	--	X
Power Base Unit (PBU)	X	X	--
Pneumatic Drive Console	--	X	--
Stroke Volume Limiter	--	X	--
Display Module or System Monitor	X	--	--
Controller Battery Module	--	X	--
Y-Connector	--	--	X
Vent Filter	-	X	--
Hand Pump	X	X	--
System Monitor	--	--	X

*HeartWear accessories include the Battery Holster, Shower Kit, Night Belt, Travel Case and Pocket Pak.

continued

8.1 Treating the Percutaneous Tube Exit Site

- Adhere to aseptic technique any time the exit site is inspected, dressed, or otherwise handled.
- Keep the exit site clean and dry.
- Establish and follow daily exit site care using a persistent antiseptic cleaning agent, such as chlorhexidine-containing scrub solutions.
- After cleansing, dry the exit site to avoid tissue maceration.
- Never apply prophylactic topical agents (such as silver sulfadiazine or polymixin-neomycin-bacitracin) to the exit site, as these agents may macerate the tissue.
- Apply a sterile bandage to the exit site at least daily.
- Immobilize the Percutaneous Tube with abdominal wraps or binders to reduce trauma to the exit site, especially when the patient is ambulatory, because trauma to the exit site will increase the risk of infection.
- Withdraw all intravascular lines as soon as practical to reduce the risk of systemic infection.
- Administer parenteral treatment with antibiotics or surgical drainage, as indicated, in patients with evidence of pump pocket infection.

Note: Fungal infection resulting from organisms such as *Candia albicans* may be associated with vegetative growth on the device. Persistent system fungal infection (refractory to antimicrobial treatment) may necessitate LVAD replacement.

8.2 Anticoagulation Therapy

Heparin is NOT routinely used after device implantation, unless low flow conditions (stroke volume < 30ml) persist, or if medically indicated. Following reversal of the heparin intraoperatively (see note below), 10% low molecular weight dextran is indicated until the patient can accept oral medication. Inhibition of platelet activity throughout the remainder of implant is maintained by administering 75mg of dipyridamole three (3) times daily (t.i.d.) and 80mg aspirin once daily (q.d.), if not contraindicated.

Note: As part of the LVAD implant procedure, heparin is administered to the patient during cardiopulmonary bypass to minimize the risk of intraoperative thrombus formation. Once the device is successfully implanted and adequate stroke volume is achieved, protamine is administered to reverse the effects of heparin.

CAUTION !

A persistent Stroke volume of < 30ml may require anticoagulation to prevent possible thrombus accumulation.

WARNING !

In the event that the SNAP-VE LVAD stops operating, all attempts must be made immediately to restore pump function using electric or pneumatic activation. In the event that the SNAP-VE LVAD stops operating and blood is stagnant in the pump for more than few minutes (depending on the coagulation status of the patient) there is a risk of stroke or thromboembolism if or when, the device is restarted.

8.3 Diagnosing a Blood Leak

A blood leak from any implanted component of the SNAP-VE LVAS is typically identified through the presence of one or more of the following symptoms:

- Unexplained internal bleeding (beyond the perioperative period following implant), possibly with painful distention of the abdomen.
- Blood draining from the Percutaneous Tube exit site, external to the tubing.
- Evidence of decreased hemoglobin/hematocrit.

Note: These symptoms may also occur due to bleeding from native tissue.

WARNING !

There is a risk of embolism at device explant or reoperation if manipulation of the device or cannulae is performed before initiation of cardiopulmonary bypass and stoppage of SNAP-VE LVAD pumping.

8.4 Right Heart Failure

Some patients suddenly develop right ventricular (RV) failure during, or shortly after, device implantation. The onset of RV dysfunction often is accompanied by the inability of the SNAP-VE LVAD to fill and by drastically reduced flow rates. Limited LVAD filling is further exacerbated in the presence of right heart failure with an elevated trans-pulmonary pressure gradient or high pulmonary vascular resistance.

CAUTION !

Right heart failure can occur following implantation of the device. Right ventricular dysfunction, especially when combined with elevated pulmonary vascular resistance, may limit SNAP-VE LVAS effectiveness due to reduced filling of the LVAD.

Treatment for right heart failure typically consists of inotropes to augment RV contractility, fluid management, hyperventilation, and pharmacological modulation of pulmonary vascular resistance (i.e., nitric oxide). As a last resort, a right ventricular assist device (RVAD) may be employed.

8.5 Avoiding Static Electric Discharge

Following implant, patients should avoid potential sources of strong static discharges (e.g., television or computer monitor screens). In addition, patients should not engage in activities that may generate static electricity (e.g., vacuuming). Exposure to strong static discharges can damage the electrical parts of the system and cause the SNAP-VE LVAD to stop.

9.0 Patient Discharge

Patients discharged to home or other non-hospital setting, must be trained in system use, maintenance, and trouble-shooting as described in the *HeartMate SNAP-VE LVAS Operating Manual* and *Patient Handbook*. In addition, because device malfunction may necessitate emergency treatment, patients should never be more than two (2) hours from a HeartMate LVAS healthcare facility.

The following equipment is required for patients residing outside a hospital setting:

Equipment	Primary (required)	Back-Up (required)	Optional
Implanted SNAP-VE LVAD	X	--	--
System Controller	X	X	--
Rechargeable Batteries (2 sets)	X (2 sets)	--	X
Emergency Power Pak (EPP)	--	--	X
HeartWear Accessories*	X	--	X
Power Base Unit (PBU)	X	--	--
Battery Clips	X	--	--
Display Module	--	--	X
Y-Connector	--	--	X
Vent Filter	--	X	--
System Controller Battery Module	--	X	--
Hand Pump	X	--	X
Patient Handbook	X	--	--

*HeartWear accessories include the Battery Holster, Shower Kit, Night Belt, Travel Case and Pocket Pak.

CAUTION !

A back-up System Controller, spare Batteries, and the Hand Pump must be with an LVAS patient AT ALL TIMES for use in an emergency.

End of Section 4

10.0 Device Explant and Replacement

1 Place patient on cardiopulmonary bypass and establish flow.

2 To stop the LVAD from pumping, disconnect power from the System Controller, then disconnect the System Controller from the Percutaneous Tube.

WARNING !

There is a risk of embolism at device explant or reoperation if manipulation of the device or cannulae is performed prior to initiating cardiopulmonary bypass and stopping the pump.

3 Expose SNAP-VE LVAD and carefully dissect it free.

4 Cut eyelet sutures connecting the LVAD to the abdominal wall or fascia.

5 Cross-clamp the Outflow Graft Conduit just distal to the Bend Relief, and then divide the graft.

6 Divide the ligatures securing the Apical Sewing Ring to the Inflow Valve Conduit, and remove the Inflow Valve Conduit from the ventricle.

7 Dissect the Percutaneous Tube between the SNAP-VE LVAD body and the abdominal wall.

8 Cut the Percutaneous Tube and remove the externalized portion.

CAUTION !

The Percutaneous Tube at explant is not sterile and care must be taken to avoid contamination of the sterile field. The cut-off fingertips of a sterile, non-powdered glove may be placed on the ends of the tube (once tube is cut) to minimize the risk of the tube contacting and contaminating the sterile field.

9 Remove the SNAP-VE LVAD from the abdomen or preperitoneal pocket and remove the remaining portion of the Percutaneous Tube, from-the-inside-out, by careful dissection.

10 Close Percutaneous Tube exit site in standard fashion.

continued

10.0 Device Explant and Replacement continued

11 Remove Outflow Graft remnant from aorta and repair the anastomosis site.

12 Return explanted LVAD and external system components to Thoratec Corporation, using Explant Kit provided by Thoratec.

Note: Directions for proper handling and return are included in the kit.

11.0 Service

Thoratec Corporation's highly-trained customer service representatives, technicians, and engineers are available to provide additional training in the use of HeartMate products and procedures, and to answer questions on a routine and emergency basis.

For information regarding Thoratec's client support services, contract your local Thoratec representative or contact Thoratec directly.

End of Section 5 

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Product Testing and Classification

The HeartMate SNAP-VE LVAS has been thoroughly tested and classified by Underwriters Laboratories (UL) and TUV Product Service (TUV PS) to fire, casualty, and electric shock hazard requirements of UL 2601-1 and IEC 601-1 standards for safety.

These standards require making the following declarations and stating the type and degree of protection for listed hazards:

Mode of Operation	Continuous
Method of Sterilization	100% EtO for blood pump and all sterile accessories
Type of protection against electrical shock	Class I (grounded) and internally powered
Degree of protection against electric shock	Type CF (Cardio Floating)
Degree of protection against harmful ingress of water	Controller - IPX3 PBU - IPX0

Medical Electric Equipment with respect to electric shock, fire mechanical and other specified hazards only in accordance with UL 260-1 and CAN/CSA C22.2 No.601-1 7D72

Authorized European Union Representative

A.D. Krauth GmbH
Krauth Medical KG
Fachbereich Cardiovascular
Postbach 70 12 60
D22012 Hamburg
Germany